# EXHIBIT 54

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

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In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:
All Actions MDL No. 15-2666 (JNE/FLM)

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DEPOSITION OF DR. ANDREA KURZ
VOLUME I, PAGES 1 - 235
JANUARY 12, 2017

(The following is the deposition of DR. ANDREA KURZ, taken pursuant to Notice of Taking Deposition, via videotape, at the Cleveland Clinic, E Building, Conference Room E3-40B, 9105 Cedar Avenue, Cleveland, Ohio, commencing at approximately 10:11 o'clock a.m., January 12, 2017.)



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PROCEEDINGS

(Witness sworn.)

DR. ANDREA KURZ

called as a witness, being first duly sworn, was examined and testified as follows:

ADVERSE EXAMINATION

BY MR. ASSAAD:

Q. Good morning, Dr. Kurz. My name's Gabriel Assaad and I represent the plaintiffs in a multi-district litigation that's being held in Minnesota.

Let us begin by if you could just state your full name for the record.

**A. Andrea Kurz.**

Q. And what is your current business address?

**A. Actually this building, so it is 1500 Euclid Avenue, Cleveland. And I'm always getting mixed up if it's 43193, I think.**

Q. That's fine. We don't -- that's -- that's close enough.

Have you ever had your deposition taken before?

**A. No.**

Q. Okay. I'm going to go through a few ground -- ground rules, and first and foremost, let's try to wait for each -- each person to finish their



question and answer before the other one speaks so we have a clear record for the court reporter. Do you understand?

**A. I do.**

Q. Okay. Second, please, when you answer, answer verbally. "Mm-hmm" or "uh-huh" doesn't really get written down well by the court reporter; it's much easier for him just to have a verbal answer. Do you understand?

**A. Uh-huh. Yes.**

Q. Finally, I'm going to ask you numerous questions today. If you don't understand my question, please let me know. Fair enough?

**A. Yes. Sure.**

Q. If you answer my question, I will assume that you understood the question. Fair?

**A. Yes.**

Q. Any time you want to take a break, that is fine, but please request a break after a question and answer has been -- has been completed. Fair enough?

**A. Yes.**

MR. ASSAAD: I'd like to mark as Exhibit No. --

THE REPORTER: 237.

MR. ASSAAD: -- 237 --



(Exhibit 237 was marked for identification.)

BY MR. ASSAAD:

Q. Exhibit 237 is a copy of your curriculum vitae that I -- I received through discovery from your office in the past few months. Is this a current copy of your curriculum vitae?

**A. One second.**

**Almost, yes.**

Q. "Almost." When you say "almost," what's missing?

**A. A few publications.**

Q. Any currently ongoing research that is missing from this curriculum vitae?

**A. Yes.**

Q. What's missing?

**A. Oh, there are -- I --**

**I can't tell you exactly. I know that I have over 200 papers by now, so which ones exactly the ones are that are missing, I don't know.**

Q. Well let me -- let me see if --

The last page is "CURRENTLY ONGOING RESEARCH."

**A. Oh, the current. Yeah.**

Q. Is there any currently ongoing research



that's not on this list that you're doing for 3M at this -- at this moment?

**A. There might be a retrospective study about predictors of hypothermia which is not on there yet, and then there is one study with 3M which we'll be doing in China that hasn't started yet and so that is not on there yet.**

Q. Is that the Protect?

**A. Yes, that's the Protect trial. Exactly.**

Q. Any study that you're doing with 3M that deals with hypothermia and infection rates?

**A. The Protect.**

Q. Okay. So doctor, can you just briefly describe your background, starting off -- or your educational background, going with college to medical school, residency.

**A. So I went --**

**I grew up in Vienna, Austria, so I actually didn't go to college because we don't have that there. After high school or gymnasium I did medical school in Vienna, thereafter did a research fellowship in -- actually, after med school I started residency in Vienna. In the fourth or fifth year of residency, started a research fellowship at the University of San Francisco -- of California in San Francisco.**

Q. And what year was that, the research fellowship?

You can look at your CV.

**A. I think it started --**

**I should know that. It started from '93 to '96.**

Q. Okay.

**A. Then I --**

Q. You were actually in San Francisco at that time?

**A. Yes.**

Q. Okay. I just -- I don't mean to interrupt. I'll try not to do that in the future. But according to your CV, it says your education, University of Vienna, 1990 to 1994.

**A. Yeah.**

Q. So your --

**A. That overlaps.**

Q. Overlaps. Okay.

Continue.

**A. So thereafter I went back to Vienna, got my professorship there. Then --**

Q. And what year was that?

**A. '96.**

**Then in '98 or '99 -- I have to look it up**



**almost -- I went to Washington University in St. Louis as Director of the Division of Clinical Research there. Thereafter, was recruited in 2004 or '3 as the chair of the Department of Anesthesia at the University of Bern in Switzerland -- and now I don't know when it was exactly, but I think it was '3, end of '3, beginning of '4 -- and in 2007 left Switzerland and joined the Department of Outcomes Research here at the Cleveland Clinic.**

Q. So since 2007 you've been here at the Cleveland Clinic?

**A. Yes. And I was vice chair of the Department of Outcomes Research, and in 2014 I became chair of the Department of General Anesthesiology within the Anesthesia Institute here.**

Q. Okay. So 2014 you became chair of General Anesthesia --

**A. General Anesthesia here.**

Q. That's not part of Outcomes Research; correct?

**A. It's not part of Outcomes Research, no.**

Q. Do you have a clinical practice right now?

**A. Yes, absolutely.**

Q. What percentage of your time are you dealing with your clinical practice as compared to dealing



with your work at Outcomes Research?

**A. My clinical practice is 50 percent, the rest is administration, and part of that is research, and that's when I -- when we collaborate with Outcomes Research.**

Q. And --

**A. So I can't give you a percentage exactly.**

Q. That's fine.

And -- and going back to the instructions, I -- I don't want you to guess, I don't want you to speculate. If you don't know the answer, it's perfectly fine --

**A. Uh-huh.**

Q. -- to say "I don't know." Fair enough?

**A. Yes.**

Q. All right. With respect to your clinical practice, can you describe your clinical practice?

**A. I work in the operating rooms and anesthetize patients 50 percent of my time. When I do that I usually either supervise residents or nurse anesthetists. And that's pretty much it, I think.**

Q. Are you in a certain -- do you --

Do you handle more than -- like one type of surgery or the other?

**A. Mainly urology, but otherwise everything.**



Q. When you -- okay. When you say "mainly urology," what percentage of your -- of your clinical practice is anesthizing -- anes -- anesthesia patients -- dealing with anesthesia patients in urology?

**A. Approximately 60 percent.**

Q. Do you handle any anesthesia services for orthopedic patients?

**A. I work there, yes.**

Q. So you --

**A. Very little.**

Q. Okay. And I'm --

Now would that include total hip and total knee arthroplasty?

**A. Yes.**

Q. Do you use forced-air warming with all your patients?

**A. Yes.**

Q. And it's my understanding that Cleveland Clinic has gone from the Bair Hugger to the Mistral system.

**A. Yes.**

Q. Do you know when that occurred?

**A. Not exactly, no.**

Q. Can you give me a rough estimate?

**A. Two years ago.**
Q. Were you in the decision-making process to change from the Bair Hugger warming unit to the Mistral?
**A. Yes.**
Q. Why did -- why did Cleveland Clinic change from the Bair Hugger warming unit to Mistral?
**A. Cost.**
Q. Is that the only reason?
**A. That was the only reason, yes.**
Q. How much cheaper is the Mistral to use than the Bair Hugger?
**A. It's a few dollars. I cannot tell you what exactly it is.**
Q. A few dollars per blanket?
**A. Per blanket.**
Q. Okay. Does -- does Mistral place the warming units like -- like 3M does?
**A. Yes.**
Q. What role did you have in the decision-making process?
**A. Only advisory.**
Q. Are you on the advisory board for the 37Company?
**A. Currently, I don't know.**



Q. At any point?
**A. I was, yes.**
Q. Okay. And did any discussion during this period of time in the decision making deal with the efficacy of the Mistral system as compared to the Bair Hugger system?
**A. Yes.**
Q. And what was discussed?
**A. It was just that I believe that they are both equally -- that the efficacy is the same for both systems.**
Q. Are you aware that the Mistral system has a HEPA filter?
**A. No.**
Q. Do you know what HEPA filter the Bair Hugger system has?
**A. No.**
Q. Do you know what a HEPA filter is?
**A. No. No, I don't. What is it?**
Q. If you don't know, we don't need to go into it.
At any time during the decision-making process, did you yourself meet with any of the representatives or salespeople from Stryker?
**A. No, I don't think so.**



Q. Was there any discussion as to the benefits of using the Mistral system, besides cost, compared to the Bair Hugger system?
**A. No.**
Q. With respect to the change from the Bair Hugger system to the Mistral system, were you in favor of the change, against the change, or indifferent?
**A. I was fairly indifferent.**
Q. Did you provide any opinion with respect to whether or not Cleveland Clinic should change from the Bair Hugger warming system to the Mistral warming system?
**A. No.**
Q. Was it when you did your fellowship in San Francisco between 1993 and 1996 that you be -- that you met Dr. Sessler?
**A. Yes.**
Q. Did you know Dr. Sessler before that?
**A. Yes, I did.**
Q. How?
**A. Oh, through a -- through my research.**
Q. When you were at the University of Vienna?
**A. Of Vienna, yes.**
Q. And what was your research in at the University of Vienna?



**A. We did the very first -- one of the first Bair Hugger studies in Europe looking at whether one can keep patients normothermic with the Bair Hugger as opposed to not using anything, which was the standard of care at that point in time.**
Q. Okay. Well when you say "not using anything," you'd use blankets.
**A. Yeah, operating room blankets, yeah.**
Q. Yeah.
**A. Yeah, yeah, yeah.**
Q. And what study was that?
**A. That should be at the very beginning of my publications. Let's see. I think it was the first one, "Forced-Air warming maintains intraoperative normothermia better than circulating-water mattresses" in Anesthesia & Analgesia. Yes.**
Q. Okay.
**A. Uh-huh.**
Q. So you -- you compared forced-air warming compared to circulating-water mattresses?
**A. Yes. I guess that was the standard of care at that time, yes.**
Q. Okay. And how was it that you became involved in this type of area of medicine on normothermia?

**A. I think by coincidence. It was just that forced-air warming was introduced at the University of Vienna, and whenever you -- I wanted to do research, and whenever you introduce a new system, you study it first, and I -- I guess it was probably one of my mentors there that suggested that I would participate in that study.**

Q. Did you lead the study? Were you --

**A. Yes.**

Q. Okay. How was --

Do you recall how forced-air warming -- or who introduced forced-air warming, the Bair Hugger system, to the University of Vienna?

**A. Yes, I do.**

Q. Who?

**A. It was a company that is called or was called Gepa-Med, G-e-p-a-Med.**

Q. Okay. And to your recollection, was that the first time that forced-air warming was used intraoperatively?

**A. Yes. In Austria.**

Q. In Austria, okay. And GepaMed or whatever the name --

**A. GepaMed.**

Q. Where is that company from?



**A. Vienna.**

Q. Vienna. Okay.

Did there ever come a time that you had dealings with Augustine Medical?

**A. Yes.**

Q. When was the first time that you had any type of interactions with Augustine Medical?

**A. It --**

**I don't know exactly. It might have been during that study, or after I started my fellowship in San Francisco.**

Q. And is that when you first met Scott Augustine?

**A. Yes.**

Q. Okay. Did you meet Scott Augustine in -- in Vienna or in San Francisco for the first time?

**A. I think in San Francisco.**

Q. Okay. That would be around 1993?

**A. I cannot remember the year, but --**

Q. Okay.

**A. -- during that timeframe.**

Q. Okay. And on your CV on page 17 --

**A. Uh-huh.**

Q. -- there is a -- under corporate sources of funding --



**A. Uh-huh.**

Q. -- on the last one there, it's "Fellowship, Augustine Medical, $100,000." Do you see that?

**A. Uh-huh.**

THE REPORTER: Your answer?

MR. ASSAAD: Is that a yes?

MS. DIFRANCO: Yes.

THE WITNESS: Yes.

Q. Okay. What was that for?

**A. '94. I don't exactly know. It was during my fellowship, so they might have supported the fellowship at the lab there. But I can't remember exactly.**

Q. Okay. Did this have anything to do with any type of funding for your 1996 New England Journal of Medicine study?

**A. No.**

Q. Well you agree that if it --

It was most likely for funding or sponsoring research for normothermia and forced-air warming.

**A. It was for funding research for physiology in regards to normothermia.**

Q. Was any paper published as a result of this funding?

**A. I assume that there were many papers**



**published as a result. I published about, I can't remember, 15 papers during these three years.**

Q. And during those three years, did you have a clinical practice as well?

**A. No.**

Q. It was pure research?

**A. Yes.**

Q. This hundred thousand dollars, was this money that went into your pocket or went towards the univer -- towards the university?

**A. It went towards the university.**

Q. Your New England Journal of Medicine article -- Medicine article of 1996, was that funding from peer-review or corporate sponsors for that research, do you recall?

**A. I don't. I don't. That must have been --**

**The study happened in Vienna, and so I assume we had barely any funding for that study --**

Q. Okay.

**A. -- at that point in time.**

Q. Do you know whether or not Augustine Medical was involved in any way in that study?

**A. I don't.**

Q. And with respect to the -- your 1996 New England Journal --

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I'm going to call it the Kurz study of 1996.
**A. That is totally fine.**
Q. Huh?
**A. That is fine.**
Q. In your 1996 Kurz study, the Kurz study, were you the lead --
**A. Yes, I was.**
Q. -- researcher?
**A. Uh-huh.**
Q. Yes?
**A. Yes.**
Q. Okay. What role did Dr. Sessler have in the 1996 Kurz study?
**A. He was a senior researcher, so he was my mentor.**
Q. Did he have any -- strike that. Withdraw. Going to page --
Well before we get there, do you currently consult for 3M?
**A. Yes.**
Q. How long have you consulted for 3M?
**A. I don't know exactly. Three, four years, five years.**
Q. Have you ever consulted for Arizant Medical?
**A. I don't remember. I might.**

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Q. Who else do you do consulting services for or on the advisory panel for?
**A. Currently, only one other company that is here in Cleveland.**
Q. Mercury Biomed?
**A. Yes.**
Q. And it's my understanding that they're in the process of -- or negotiating a process of being purchased by another company.
**A. I heard about that.**
Q. And that's how you received documents with respect -- some due diligence documents to review from -- from the company that -- that was acquiring Mercury Biomed. Do you recall that?
**A. No, I did not.**
Q. It's documents that you produced to me, but it's irrelevant.
And what technology do they have? Do they deal with warming patients?
**A. Yes, they do.**
Q. And what technology do they have?
**A. It's a -- it's a conductive warming system by warming hands and feet; however, it also has a -- a -- a second physiological thing to it, it has a spine warming part with the idea that warming the**

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**spine in the neck area vasodilates the periphery and -- and therefore the periphery, meaning hands and feet, are easier to warm.**
Q. Okay. And the inventor of that technology is Dr. Diller; correct?
**A. Yes.**
Q. Okay. And it's my understanding that there's already been one clinical trial that it has gone through.
**A. There's been one observational study, yes.**
Q. Okay. And are there -- is there a plan --
Is there any plans for another study?
**A. There is a plan for a volunteer study, yes.**
Q. Okay. And what were the results of the first observational study?
**A. Unclear.**
Q. Why do you say "unclear?"
**A. Because we evaluated in patients vasomotion in the per --**
**So we wanted to show in patients under anesthesia whether spine warming truly causes vasodilation, and under anesthesia many other things have been other than warming, so it's --**
**The data at this point is very hard to evaluate and that's why I say it's unclear. It's just**

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**that patients who are diabetic react differently, patients who need vasopressors react vaso -- react differently, so I think it's uninterpretable.**
Q. Okay. And is Dr. Sessler also on the advisory board for Mercury Biomed?
**A. I believe so.**
Q. Okay. So currently my understanding is you're on the advisory board or panel for 3M and Mercury Biomed; correct?
**A. Yes.**
Q. How about in the past, who have you been on the advisory board for?
**A. Good question.**
Q. Well we know 37Company is one of them; correct?
**A. We know 37Company. You know, I -- I don't think I recall anything else.**
Q. VitaHEAT?
**A. Vital --**
Q. VitaHEAT.
**A. No.**
Q. Okay.
**A. Which company is that?**
Q. That's its own company, VitaHEAT.
**A. Okay.**

Q. What about PerfecTemp for --
**A. No, I don't even know.**
Q. Medline?
**A. Medline?**
Q. Uh-huh.
**A. No.**
Q. Okay. So anyone else that you can think of that deals with patient warming?
**A. No.**
Q. Now going back to your funded research, you break it up into peer-reviewed sources and corporate sources; correct?
**A. Uh-huh.**
Q. Yes?
**A. Yes.**
Q. Why do you do that? What's the difference?
**A. There is --**
**First of all, it's the way how you -- or how we, at least in the medical field, write our CVs. There's a very different review process and negotiation process with corporate and peer-reviewed sources, and so I guess all the peer-reviewed ones are considered to be on a higher scientific level.**
Q. The peer reviewed?
**A. Yeah. And that's why you want to know**



**whether an investigator has only corporate funding or mainly peer-reviewed funding.**
Q. But I recall you wrote an article that peer-reviewed funding is also the most susceptible to fraud.
**A. Peer-reviewed funding?**
Q. Uh-huh.
**A. I don't think I said that.**
Q. Or -- or research, research initiated by investigators as compared to -- which is more peer -- peer-reviewed, as compared to corporate is more susceptible to fraud. Is that true?
**A. I think I wouldn't phrase it that way, and I would be surprised that I phrased it exactly that way.**
Q. And I could be misquoting and I -- I'll pull up the article.
**A. No, you are right. I wrote an article, but it would be great if you had it because I don't think I said it that way. I think what we might -- what I might have said --**
MS. DIFRANCO: Why don't you wait.
THE WITNESS: Yeah.
MS. DIFRANCO: He doesn't want to have you guessing.
THE WITNESS: Oh.



(Discussion off the stenographic record.)
(Exhibit 238 was marked for identification.)
BY MR. ASSAAD:
Q. What's been marked as 238 is an article written by you and Dr. Sessler entitled "Departmental and Institutional Strategies for Reducing Fraud in Clinical Research."
**A. Uh-huh.**
Q. Do you recall this article?
**A. Yes.**
Q. If you look at page 475, --
**A. I see that.**
Q. -- at the second column, second --
**A. Uh-huh.**
Q. -- paragraph, starts with, "The risk of fraud is probably greater for investigator-initiated studies than for trials conducted by corporate sponsors." Do you see that?
**A. Yes, I do see that.**
Q. What did you mean by that?
**A. It actually says thereafter --**
**Anyway, the -- the reason is the sponsors have legal obligations to assure that the valid -- validity of the data is correct. And if you read the**



**beginning of the article, it describes our structure in the Outcomes Research department here, and it does say that in previous times when single people would do a study completely by themselves, that they wouldn't knowledgeably do fraudulent work, but they would maybe -- not always -- abide to strict rules of randomization, blinding, et cetera, and that's -- that's what's meant by that, and therefore, we at the Outcomes Research department have all the structures to avoid this kind of thing.**
Q. Whether it's --
**A. Whether it's --**
Q. -- peer investi -- or investigator or corporate.
**A. Yes.**
Q. Fair enough.
On -- on the disclosures it says, "This manuscript was handled by: Steven L. Shafer M.D." Do you know who that is?
**A. Yes. He was at that point in time the editor of the journal Anesthesia & Analgesia.**
Q. Okay. Is he a friend of Dr. Sessler's?
**A. I know that they know each other well. Whether --**
Q. Have you met --

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Sorry, go ahead.
**A. Whether they're friends, I don't know.**
Q. Okay. And when it says, "This manuscript was handled by: Steven L. Shafer," what part of it was he involved in?
**A. He is edit -- editor of Anesthesia & Analgesia. He gets all articles that are submitted to the journal and then either hands them on to other editors or deals with them himself.**
Q. I -- I understand that, but --
And maybe I just don't know. But I've seen other articles in other peer-reviewed publications and I've never seen anything where it says the manuscript was handled by the -- like the editor in chief or the main editor of -- of the -- of the publication. Why is it different in this publication as compared to other publications?
MR. GORDON: Object to the form of the question.
MS. DIFRANCO: Go ahead, if you know.
**A. I -- no, I don't know. I can --**
**I think it is because it's an open-mind article. This is not a research paper, --**
Q. Okay.
**A. -- this is just an opinion.**

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Q. Fair enough.
MS. DIFRANCO: And doctor, I think Mr. Assaad wants to know what you know. If you don't know something, you just tell him that's what --
THE WITNESS: Uh-huh.
MS. DIFRANCO: He doesn't want you to guess.
MR. ASSAAD: I don't want you to guess or speculate.
THE WITNESS: Yeah.
Q. And -- and you said that peer-reviewed research is at the highest level as compared to corporate.
**A. I consider it at a higher level, yes.**
Q. When you say "a higher level," what do you mean?
**A. Scientifically. So I mean these are usually investigator-initiated studies that have been reviewed by major experts in the field, so if you get then funding from an NIH, which is the highest peer-reviewed funding we have, it's enormously meaningful.**
Q. And you agree that -- that corporate-funded research may or may not have some commercial purpose to it; correct?
MR. GORDON: Object to the form of the

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question.
Q. Let me rephrase. It was a bad question.
**A. I'm not sure. Yeah.**
Q. Is corporate-funded research -- let me ask it more openly.
**A. Uh-huh.**
Q. Why would corporate-funded research not be at such a high level as peer-reviewed research?
**A. I said I might consider it not as high.**
Q. In your opinion then.
**A. In my opinion. Ideally, corporate-funded research will be scientifically at the exact same level as any other type of research.**
Q. Do you agree with me that some corporate-funded research is commercially motivated?
**A. I agree.**
Q. And in fact would you agree that most corporate-funded research has some sort of commercial motivation?
MR. GORDON: Object to the form of the question, also lack of foundation.
MS. DIFRANCO: Go ahead and answer.
**A. I would say some of it is. I don't want to say most of it is.**
Q. Can you sit here today and identify one

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company that has -- that you've received research from that didn't deal with any type of product or technology or anything with the -- with the company business?
**A. I don't think so.**
Q. So you agree with me that the majority of corporate-funded research has some sort of commercial purpose to it.
**A. Yes.**
Q. Now I will assume, unless you tell me otherwise, that all of your research and the publications abide by kind of like the standards that you've written out in the document of Exhibit 238 titled "Department -- Departmental and Institutional Strategies for Reducing Fraud in Clinical Research."
**A. Yes.**
Q. Sitting here today, you -- there's nothing on your CV that you would look back and say it doesn't meet the current standards of -- of clinical strategies outlined in your article of Exhibit 238; correct?
**A. That's not correct.**
Q. What's -- what's not correct about that statement?
**A. The research standards have greatly changed**

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**over the past 25 years, so what was standard of care in the clinical world -- what was standard of care 20 years ago, was absolutely correct then, might not be now.**

Q. Okay. But sitting here today, you stand by -- you stand behind all your publications; correct?

**A. Absolutely.**

Q. Okay. Are there any publications dealing with forced -- normothermia that sitting here today -- withdraw that question.

For example, the 1996 Kurz study that was done by you, would that comply with today's standards with regard to departmental and institutional strategies for reducing fraud in clinical research outlined in Exhibit 238?

**A. I actually believe so.**

Q. You hesitated. Why was that? You say you absolutely believe so. Is there --

**A. Yeah. Because it was done under very different circumstances.**

Q. Okay. In any of your research or publications that were corporately -- funded by corporations, do you allow those corporations to have any editorial input with respect to publications?

**A. We allow, per contract, all the companies to**

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**read the publications and to -- before we publish it. That's a Cleveland Clinic rule.**

Q. Do you allow them to make changes?

**A. In general, not.**

Q. But you have in the past?

**A. I should believe no, no.**

Q. Do you know whether or not Dr. Sessler has allowed a corporation to make changes to publications before they were published?

**A. I don't know.**

Q. Have you ever not published or submitted a manuscript for publication based on the request of a corporation that funded the study?

**A. Could you phrase -- rephrase that? Sorry.**

Q. Have you ever done research or done a study --

**A. Uh-huh?**

Q. -- that had unfavorable results -- results for the corporate sponsor and have not published the study as -- as a result of a request by the corporate sponsor?

**A. I don't recall that.**

Q. Have you ever began research --

**A. Uh-huh.**

Q. -- and initially found out the results to be

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unfavorable for the cor -- for the -- the research that was being done that was funded by a corporate sponsor --

**A. Uh-huh.**

Q. -- and request the com -- and -- and stop further research as a result of a request of a corporate sponsor?

**A. That might have been.**

Q. Do you recall any specific instance?

**A. It is things that usually have been in product development. So, for example, when we worked with -- with a company like Mercury, who was developing a product, and we get it here, do a study, and we see that it's not working because the product isn't yet developed in a way, then we agree to stop, get it better developed, and do the study.**

Q. Okay.

**A. So --**

**But that's more product development side.**

Q. Has 3M ever asked you, in any publications you've ever done for them, to -- that they want to make changes to the manuscript before you submit it for publication?

**A. I believe once.**

Q. Can you please describe that.

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**A. I'm not certain that I completely remember. It was a -- it was a -- in a retrospective study about the effect of hypothermia on perioperative blood loss where they actually suggested an additional analysis, which we found to be very, very helpful. So -- so --**

**And I assume if we would not have found it helpful, that we wouldn't have done it, but it was actually an excellent idea.**

Q. And who do you -- who do you deal with at 3M?

**A. Currently, mainly with Al Van Duren.**

Q. What about Michelle Hulse Stevens?

**A. With her as well, yes.**

Q. Have you had dealings with Gary Hansen?

**A. Yes, I have.**

Q. What about the former CEO, Maharaj, does that sound familiar?

**A. It sounds familiar, but I've not dealt with him much.**

Q. Okay. Now going to your CV, I want you to turn to page 16.

**A. Hmm.**

Q. If you go down to the sixth or seventh --

**A. Uh-huh.**

Q. -- the seventh research, it says, "A

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comparison study of vital HEAT (vH2) Temperature Management System to upper-body forced-air warming in patients undergoing open colectomy under general anesthesia." Do you see that?

**A. Yes, I do.**

Q. And I guess the principal investigator is Dr. Sessler.

**A. Uh-huh.**

THE REPORTER: Your answer?

Q. Yes?

**A. Yes.**

Q. And the company is LMA?

**A. Yes.**

Q. Do you know who LMA is, or what that stands for?

**A. I can't remember, no.**

Q. Okay. Do you recall doing this research for -- on the -- on the vital HEAT?

**A. I do.**

Q. Okay. And you received $250,000 to conduct the research; correct?

**A. Yes.**

Q. And also it's in 2008 and 2009; correct?

**A. I assume.**

Q. Okay. What do you recall about this

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research?

**A. I think this was a study -- and I would have to look it up -- that was performed -- Vital HEAT. You know what? I have to guess now, so no.**

Q. Okay. Do you know -- do you know what the vital HEAT Temperature Management System is?

**A. I do know what it is.**

Q. What is it?

**A. It was an arm/hand warming system that applied heat and negative pressure to an arm.**

Q. Just one arm?

**A. Yes.**

Q. Okay. And what were -- Do you recall the results of that study?

**A. I believe it was almost as effective as forced air.**

Q. Okay. And that didn't blow any air; correct?

**A. Hmm?**

Q. It didn't blow any air. It wasn't forced --

**A. No.**

Q. Okay.

**A. No, it was not.**

Q. Was a paper published?

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**A. Yes.**

Q. Can you point to me the paper?

**A. Yeah. Two eight nine, two eight nine. Who was the first author? Yeah, number 102, "...Normothermia During -- "...Maintain Normothermia During Open Abdominal Surgery."**

Q. Okay. And just to be clear, are you saying that it was as effective as forced-air warming, or you -- because it says "Comparably." What does that mean to you?

**A. That would mean as effective, yeah.**

Q. Okay. Also on page 16, second one is "LMA-Perfect temperature versus Forced air warming," principal investigator was Dr. Sessler, company was LMA North America, you received $196,000 for that study. Do you recall that study?

**A. Not clearly.**

Q. Okay. Do you know what year that was? Because the year is missing.

**A. They are in -- in -- in ascending order, so it must have been around 2012.**

Q. And let me ask you if it's -- if it's article number 97.

**A. I'll look. No.**

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Q. Okay.

**A. Huh-uh.**

Q. Oh.

**A. Because that's too early.**

Q. Okay. If you don't know, that's fine, we can -- we can move on.

**A. Uh-huh.**

Q. And finally, going to page 15, I have a couple -- couple of other questions. The second one down is "Core temperature profiles at the Cleve -- at the Cleveland Clinic," sponsored by 3M, $75,000.

**A. Uh-huh.**

Q. Do you recall -- Is that yes?

**A. Yes.**

Q. Do you recall that study?

**A. Yes.**

Q. What study is that?

**A. That only describes, as it says, core temperature profiles in something like 50,000 patients that have been operated at the Cleveland Clinic over the past about eight years.**

Q. Is that research still ongoing?

**A. No.**

Q. Has anything been published?

**A. Yes, it has been published.**
Q. Is that the 2015 publication in Anesthesiology?
**A. Yes.**
Q. Fair enough.
**A. Yes.**
Q. And if I recall correctly, it also looked at blood loss.
**A. Yes.**
Q. Okay. And I take it during the blood loss you discussed Celsius hours; correct?
**A. Correct, yes.**
Q. Okay. And I --
My understanding of Celsius hours is how many degrees below 37 degrees multiplied by how many hours are at that time period.
**A. Exactly.**
Q. Okay. And that was predictive of the risk -- the -- the risk rate of blood loss; correct?
**A. Not blood loss, but transfusions.**
Q. Transfusions. I'm sorry, you're correct.
And if I recall correctly, in that study you also looked at length of stay, but that -- the results were not statistically significant; correct?
**A. That's --**



**Yes.**
Q. Below that you have "Target Normothermia." That's also sponsored by 3M?
**A. Uh-huh. Yes.**
Q. You're catching on.
What's that study about?
**A. That study --**
**That actually is not a study, it's a qual -- it was a quality-improvement project about looking at --**
**There were, if I know now, about 60 institutions in various different countries that measured core temperature over a three-month period, and then we evaluated just in an observational fashion the incidence of hypothermia.**
**(Discussion off the stenographic record.)**
Q. I think I recall that, and that's where you had a bunch of graphs with each country; correct?
**A. Exactly.**
Q. Okay.
**A. Yes.**
Q. I can't find it now, but I do recall that.
**A. Yes.**
Q. Fair enough.
And finally, the top one, "Pre-warming and



satisfaction in patients undergoing ambulatory surgery," $150,000 from 37Company.
**A. Yes.**
Q. Okay. And has that study been published?
**A. Yes.**
Q. And what was --
**A. Oh, I think it is in publication.**
Q. Can you describe that study, please?
**A. In this study, patients were warmed before induction of anesthesia in an ambulatory setting, with the idea that patients who were warmer before surgery will have better patient satisfaction afterwards.**
Q. So prewarming.
**A. Prewarming.**
Q. Okay. Now with respect to your articles, do you -- do you publish any particles or any articles listed in areas that you have no expertise in?
**A. No.**
Q. Okay. Would that be -- would that be sort of a fraud if you published something that you have no expertise in?
MR. GORDON: Object to the form of the question.
MR. ASSAAD: He may object, --
MS. DIFRANCO: Yeah, go ahead.



MR. ASSAAD: -- but you may answer.
MS. DIFRANCO: I'll tell you if you shouldn't.
**A. No, it would not, because you could still have some input into a paper. It's just that I do not do that.**
Q. Oh. Why don't you do it?
**A. Because I feel more comfortable with things I know things about.**
Q. Have you ever published a paper or worked on a paper as a favor for a corporation?
**A. No.**
Q. Why not?
**A. Because I -- I like doing the research myself, so --**
Q. Okay. Have you ever edited a paper that was written by a corporation and put your name on it to get it published?
**A. Not for publication.**
Q. Would you ever put your name on a paper that you weren't involved in with respect to the protocols with respect -- in beginning the research?
**A. No.**
Q. Why not?
**A. Because part of also guidelines for us are**

**that you really have a substantial intellectual contribution to a study, so --**

**Well let me rephrase that. I might put my name on a paper where I have significant contribution.**

Q. Okay. In an area that you have expertise in.

**A. Yes.**

Q. Okay. Under your authors' ethics in doing research, is it ethical to have -- to have the corporation write the first draft of the manuscript in corporate-sponsored funding?

**A. In corporate -- I --**

**Under mine, I assume not.**

Q. Why not?

**A. Just because if -- if I do research, I -- I think I want it written in my words.**

Q. Fair enough.

And in any of your research or publications, has there ever been an instance in which the first draft of the manuscript was provided to you by the corporation that sponsored the study?

**A. I don't think so.**

Q. Have you ever done research sponsored by a corporation that the outcome was a disappointing clinical result for the corporation?



**A. I can't recall. I might have. I can't recall --**

Q. I mean in all the --

**A. -- a study now.**

Q. I mean in all the studies that you've performed that were corporate sponsored, has there ever been a study which the result was not favorable to the corporate sponsor?

**A. Probably.**

Q. Okay. And --

But you don't know one way or the other?

**A. Correct.**

Q. Okay. So I don't want you to guess. So you --

**A. Yeah.**

Q. Sitting here today, you don't know.

**A. Yeah.**

Q. Okay. Have you reviewed any documents in preparation of today's deposition?

**A. No.**

Q. Have you had any discussions with anyone besides your attorney with regard to today's deposition?

**A. No.**

Q. Did you have any discussions with Dr.



Sessler about the deposition?

**A. No.**

Q. Have you had any discussions with Dr. Sessler about this case?

**A. Minimally.**

Q. Do you know what this case is about?

**A. Yes, I do.**

Q. What's your understanding of -- of the claims in this case?

**A. My understanding is that 3M -- or -- or -- or that there is a lawsuit against 3M in regards to bacterial contamination of patients undergoing orthopedic surgery, I guess hip replacements, due to bacteria generated and blown around by forced-air warming.**

Q. You have no expertise in -- in operating room airflow; correct?

**A. No. No.**

Q. And you have no expertise in orthopedic surgery; correct?

**A. No.**

Q. Do you have any expertise in periprosthetic joint infections?

**A. No.**

Q. Do you have any expertise with respect to



the causation of periprosthetic joint infections?

**A. No.**

Q. Do you have an understanding that periprosthetic joint infections are different than a -- a soft-tissue wound infection?

**A. Yes.**

Q. Okay. I assume you're familiar with host defense --

**A. Yes.**

Q. -- dealing with normothermia; correct?

**A. Uh-huh.**

Q. Yes?

**A. Yes.**

Q. All right. Do you have --

With respect to periprosthetic joint infections, do you understand that the standard of care is to remove and replace the joint? Do you understand that? Are you aware of that?

**A. Yes, I am.**

Q. Okay. And is that based on doing anesthesia for revision surgeries?

**A. Yes.**

Q. Fair enough.

And do you understand the reason is that because the host can't defend a -- a -- an infection

that has attached itself to an inanimate object such as a -- as a -- a joint, an artificial joint?

MR. GORDON: Object to the form of the question.

MS. DIFRANCO: Go ahead if you -- if you know.

**A. I would say yes.**

Q. Because there's lack of blood flow to the -- to the joint; correct?

**A. Correct.**

Q. Okay. You're familiar with that; correct?

**A. Yes, I am.**

Q. Okay. And sitting here today, you have done no studies with respect to normothermia and the incidence of periprosthetic joint infection.

**A. That's correct.**

Q. Okay. And sitting here today, you're aware of no studies conducted by you yourself or anyone in the field with respect to normothermia and incidence of infection in orthopedic surgeries.

**A. I don't know studies about that, yes.**

Q. Okay. Well you -- you're an expert in the field of normothermia; correct?

**A. Yes.**

Q. And many of the studies are conducted



probably -- like through Outcomes Research with respect to normothermia.

**A. That is correct.**

Q. Okay. And if a study comes out that is a significant study, you -- you -- you keep yourself apprised of -- of the -- the -- the -- the research that's being done and the publications in the field of normothermia; correct?

**A. Mostly, yes.**

Q. Are you also aware that the number of CFUs required to cause a periprosthetic joint infection is much less than is required to cause a wound infection?

MR. GORDON: Objection to the form of the question.

**A. I -- that -- I have no --**

Q. Is that outside your expertise?

**A. That is outside of my expertise, yes.**

Q. That's fine.

Dealing with doing anesthesia services for -- for patients that undergo total knee or total hip arthroplasty and -- and, you know, dealing with the -- with the orthopedic surgeon, are you aware that patients that undergo those procedures are more susceptible to a -- an infection?

**A. No, I'm not.**



Q. Are there different types of operating rooms in the Cleveland Clinic?

MR. GORDON: Object to the form of the question.

MS. DIFRANCO: What do you mean by "different?"

Q. Like is there an ultraclean operating room that's used for orthopedic procedures as compared to other operating rooms?

**A. It's not called ultraclean, but there might be differences in airflow, yes.**

Q. Okay. Are -- are the orthopedic procedures that are, you know, total hip or total knee done in certain operating rooms as compared to other surgeries?

**A. Yes, they are.**

Q. Where are they -- where are they performed at?

**A. Oh, they are performed here in the E Building and in ORs that have a laminar airflow technique.**

Q. Is it laminar or unidirectional, do you know?

**A. Oh, God. I don't know.**

Q. That's fair enough.



**A. Yeah.**

Q. Okay.

**A. I don't know.**

Q. Do you know why they're performed in those operating rooms as compared to other operating rooms?

**A. I actually don't, no.**

Q. Okay. So currently you consult for 3M and Mercury Biomed.

**A. Yes.**

Q. What -- what percentage of your income is derived from consulting for 3M?

**A. Barely anything.**

Q. Well how much do you get paid by 3M per hour for consulting?

**A. You know, I don't know the per-hour pay.**

Q. You receive checks from 3M?

**A. I do when I give a talk for them.**

Q. Okay. And you --

And I understand they'll pay your costs, to reimburse your costs; correct?

**A. Yes.**

Q. They also give you money for -- for a day of your time or per hour; correct?

**A. It's per day I believe.**

Q. Okay. And is it --

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**A. It could be something else.**
Q. Is it around $3,000 a day?
**A. Could be.**
Q. Okay. Well around that number, give your take?
**A. Yeah.**
Q. Okay. And that's for when you give talks or you have -- or when you go for meetings with the advise -- advisory board; correct?
**A. Exactly.**
Q. Okay. When is the last time you had an advisory board meeting with 3M?
**A. I don't know exactly, but it's -- I think it's more than two years ago.**
Q. Okay. What about discussions with 3M over the phone that's not related to research?
**A. Last one, half a year ago.**
Q. Okay.
**A. October, September.**
Q. And it's my understanding that the money that you obtain from your consulting services, giving talks, is paid to you and not to the Cleveland Clinic; correct?
**A. That is correct.**
Q. Before I leave your CV, I have a quick

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question. Maybe this will remind you of your current research for 3M.
(Exhibit 239 was marked for identification.)
BY MR. ASSAAD:
Q. What's been marked as Exhibit 239 is an e-mail from Daniel Sessler to Mark Morken, and you are also copied on the e-mail along with Michelle Stevens, and the subject is "Protocol drafts for Hypothermia-MINS retrospective analysis & Intraoperative Core Temperature and Infectious Complications after Colorectal Surgery."
**A. Uh-huh, yes.**
Q. And this was dated March 18th, 2016.
**A. Yeah.**
Q. The second one, "Intraoperative Core Temperature and Infectious Complications after Colorectal Surgery," is that the -- is that the Protect study?
**A. No, it is not. It's a retrospective analysis.**
Q. Okay. Is that ongoing right now?
**A. I hope so. Yes, I -- I think so.**
Q. Okay. And what -- what is that study?
**A. That is just a retrospective study looking**

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**at the association between intraoperative hypothermia and post-op infections, very much like the one you mentioned before about blood loss.**
Q. Okay. And what type of infections?
**A. Those are -- those are anything from superficial to deep infections --**
Q. Okay.
**A. -- according to CDC criteria.**
Q. Okay. And this is --
Are you looking at just here in the Cleveland Clinic?
**A. Yes.**
Q. Okay. So you're going through the Cleveland Clinic database.
**A. Absolutely.**
Q. Okay. And 3M is funding that?
**A. Yes.**
Q. And when you say "intraoperative hypothermia," I know there's been a big discussion of what actually is hypothermia, what degree. In your opinion, what is the degree --
What degree Celsius is considered hypothermia, below what number?
**A. I would say everything below the normal core temperature.**

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Q. Which is?
**A. Whatever you come in with; 36.7 maybe for you, 36.8 for me, whichever is your preoperative core temperature.**
Q. Okay. Fair enough. So anything below the core temperature. But when you -- when -- when you --
Let me ask it this way. This is more education for me. Is -- is that why lately you've been more going with this -- like in research, more of the delta, the change, --
**A. Yes, absolutely.**
Q. -- as compared to a hard number?
Is that a yes?
**A. Yes.**
Q. Okay. But in the 2015 study you used 37 degrees as the baseline and the delta C of one would be 36, and below that would be considered hypothermia; correct?
**A. Yes.**
Q. So you used 36 as your level --
**A. As a cutoff.**
Q. Okay. So what -- what --
So I understand your definition of hypothermia is anything below your core temperature, but for scientific purposes as in the cutoff, what do

you -- what's your opinion to use?
**A. We still use 36.**
Q. Okay.
**A. Although arbitrary.**
Q. And some people use 35.5, --
**A. No.**
Q. -- or is it 36.5?
**A. I think internationally most people use 36.5.**
Q. Okay. And when you consider mild hyp -- hypothermia, what's considered mild hypothermia, What -- what degree level before 36?
**A. I would say 36 -- 35.5.**
Q. So 35.5 to 36 is mild hypothermia?
**A. Uh-huh.**
THE REPORTER: Your answer?
Q. Yes?
**A. Yes.**
Q. And then anything below 35.5, you consider it hypothermia.
**A. Yes.**
Q. And my understanding is at 34.5, the body vasoconstricts and usually remains at 34.5 degrees; correct?
**A. Simply said, yes.**



Q. What -- what's the more complex way of saying it then?
**A. 34.5 isn't exactly. It -- it -- it depends on the patient's physiology and type and dose of anesthesia at which the patient vasoconstricts. But you are correct, 35.5 is a round, I think --**
Q. An arbitrary number that's rounded such as 36 --
**A. Yeah.**
Q. -- degrees for --
**A. It's not quite as arbitrary, no.**
Q. But my point is, I mean 36 is not an exact number for --
**A. Huh-uh.**
Q. It's a number that people use; correct?
**A. Yes.**
Q. And 34.5 is the number they use when people say patients will vasoconstrict.
**A. Exactly. Yes.**
Q. Now are you familiar with the way the Bair Hugger works --
MR. GORDON: I object to the form of the question.
Q. -- or operates?
MS. DIFRANCO: Go ahead. If you know.



**A. Roughly, yes.**
Q. You understand that it takes air in, heats up the air, goes through a hose into a blanket, and blows hot air through tiny holes over the patient.
**A. Yes.**
Q. Are you aware that the air that's being drawn from the Bair Hugger unit is -- the intake is from the bottom of the unit that's on the floor?
MR. GORDON: Object to the form of the question.
MS. DIFRANCO: Go ahead if you -- if you know.
**A. I actually don't.**
Q. Have you ever studied the Bair Hugger or looked at it?
**A. Yeah.**
Q. Have you ever felt where the air is coming in and coming out of?
**A. No.**
**What's coming out, yes.**
Q. Okay. So sitting here today, you're not aware that for the model --
Do you know what the model 750 is, the blue Bair Hugger?
**A. Yes.**



Q. Okay. And actually, you've done testing on the model 750 in some of your research; correct?
You used the model 750 as your forced-air warming device you -- you've used in research.
**A. I don't know which model we used.**
Q. Okay. Fair enough. But you are familiar with the 750 or the -- the model that's blue.
**A. I believe so, yes.**
Q. Okay. And are you aware that the intake manifold of air is on the bottom of that unit?
**A. No.**
Q. Okay. Would that cause you any concern?
**A. No.**
Q. Why not?
**A. Which difference makes -- does it make whether it's at the bottom or the top?**
Q. Is -- is the -- is the operating room floor clean?
**A. No.**
Q. Okay. Are you concerned that the air that is drawn into the Bair Hugger is -- is drawing air from the operating room floor?
**A. No.**
Q. Why not?
**A. Because nothing in the OR is truly clean,**

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**and I'm -- I doubt that the air changes much within whatever a size of the device would be. I mean --**

Q. You don't think the operating floor is not sterile?

**A. I know it's not sterile.**

Q. Okay. But the sterile site is -- is considered sterile, correct, where the operating procedure is being performed?

MR. GORDON: Object to the form of the question.

**A. Yeah. Can you --**

Q. Okay. Are you sitting here today and saying to me that -- strike that.

Are there any parts of the operating room that are considered sterile, such as the sterile field?

**A. Yes.**

Q. Okay. And you agree with me that the goal of the operating personnel is to keep the sterile field as sterile as possible.

**A. Yes.**

Q. Okay. As a result, you -- surgeons try to keep their hands above the operating room table at all times; correct?

**A. I assume.**

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Q. Okay. You don't know one way or the other?

**A. No.**

Q. I don't want you to assume. If you don't know, just say you don't know.

**A. No, not -- not the way you asked. Yes. No.**

Q. You don't know one way or the other. Okay.

**A. Yeah.**

Q. So sitting here today as an anesthesiologist, do you have any concern of whether or not any contaminants can get inside the Bair Hugger unit?

**A. I actually don't.**

Q. Have you ever thought about it before?

**A. Very little.**

Q. Have you ever been in any discussions with 3M regarding Dr. Augustine's claims about the contamination of -- of these units?

**A. I have not.**

Q. Okay. Have you ever been in any conversations with 3M regarding Dr. Augustine's claim that blowing air is risky?

**A. I -- I personally have not.**

Q. So you, sitting here today, you personally have not sat in any advisory meeting where they brought up how to -- how to defend against Dr. Augustine's claims that blowing air is risky. That's your testimony today.

**A. No.**

Q. What is your testimony today?

**A. I've been in advisory committees where it has been discussed, but that wasn't your previous question.**

Q. So you've been in advisory meetings --

**A. Yes.**

Q. -- where it's been discussed. And have you had any input on -- on those discussions?

**A. No.**

**(Discussion off the stenographic record.)**

BY MR. ASSAAD:

Q. So have you investigated or studied or done any research on whether the Bair Hugger unit itself can become internally contaminated with microbes?

**A. No.**

Q. Would that be, if it did become --

If it could become contaminated with microbes, would that be of any concern to you as an anesthesiologist using the device in the operating room?

**A. I believe -- I actually believe not.**

Q. Why not?

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**A. It's because -- I mean there are so -- there are so many -- I mean --**

**I mean if you're in an operating room, there are so many people in the room, there's so much airflow going on with or without a device that might have some bacteria in there that I would not consider it clinically relevant.**

Q. Is there any other device that you're aware of that blows air that can be contaminated onto the patient in the operating room?

**A. A warming device?**

Q. Any device.

**A. I don't know.**

Q. How many surgeries have you sat in on?

**A. How many?**

Q. How many surgeries have you done in the past where you're the anesthesiologist?

**A. Oh, many thousands.**

Q. Thousands, correct? And you have the -- the clean air coming from the top of the -- of the operating room; correct?

**A. Yes.**

Q. Okay. Are you aware of any other device that -- that blows air onto the patient besides a forced-air warming device?

**A. No.**
Q. Okay. So if the air is contaminated with microbes, you -- would you think that would be a good thing or a safe thing for the patients?
MR. GORDON: Object to the form of the question.
**A. It would --**
MS. DIFRANCO: Go ahead. Yeah, you can answer.
**A. I think it would not, but I'm not convinced it is.**
Q. You don't think it would blow contaminants onto the patient?
**A. I don't know whether it's as im --**
**Actually, I don't know. I don't know.**
Q. So as an anesthesiologist, if -- if -- if you found out or became aware that the -- the Bair Hugger device being used in your surgeries has a potential of having microbes in it, or contaminants, that would be of no concern to you.
MS. DIFRANCO: Object. You've asked and answered -- asked her three times already.
MR. ASSAAD: Well she's been back and forth. I want to get a final answer.
MR. GORDON: Move to strike counsel's



comments.
**A. I have no concerns in regards to that question.**
Q. Fair enough.
MR. ASSAAD: We can take a break.
THE REPORTER: Off the record, please.
(Recess taken.)
BY MR. ASSAAD:
Q. I'd like to show you what's been marked as Exhibit 66.
(Discussion off the stenographic record.)
Q. Exhibit 66 is an e-mail from Al Van Duren to Mark Scott, Gary Hansen and Dave Westlin entitled -- or dated February 20, 2009. Just please review this e-mail front and back.
**A. Oh, I start in the back?**
**Uh-huh.**
Q. Okay. If you look --
If you go to the back, it seems back on February 20th, 2009, the Director of Materials Management at Memorial Hermann Hospital in Texas took a culture of a model 750 unit Bair Hugger. Do you see that --
**A. Uh-huh.**
Q. -- on the final --



Yes?
**A. Yes.**
Q. And it cultured positive for Acinetobacter?
**A. Yes.**
Q. Out of curiosity, do you know whether or not Cleveland Clinic cultures -- or gets random cultures of their Bair Hugger units to see if there are any microbes on them?
**A. I don't know.**
Q. Okay. And -- and the title of this --
The subject matter of this -- of this e-mail chain is called -- or exchange is "Contaminated?" from where Mathieu, Rick, sends it or forwards it to someone at 3M. Do you see that?
**A. Yes.**
Q. Okay. Were you aware that the Bair Hugger blowers can become contaminated --
MR. GORDON: Object to the form of the question.
Q. -- prior to this e-mail?
MR. GORDON: Objection to the form -- form of the question, also lack of foundation.
MS. DIFRANCO: Go ahead.
**A. I --**
**Yeah.**



Q. You were aware prior to this e-mail that Bair Hugger units can become contaminated?
**A. Prior to you showing me that.**
Q. Yes. Prior to today --
**A. Yes.**
Q. -- were you aware that Bair Huggers can become contaminated?
**A. I have heard about it, yes.**
Q. How did you hear about it?
**A. Oh, I don't know.**
Q. Has that caused you any concern with respect to the use of the Bair Hugger unit?
**A. No.**
Q. All right. Do you see on the top of the e-mail, the last e-mail, it says from Al Van Duren?
**A. Uh-huh.**
Q. And you -- you know who Al Van Duren is; correct?
**A. Yes, I do.**
Q. Okay. It says, "Remove and discard the filter (in the biohazardous waste)."
**A. Yes, I see.**
Q. Okay. Do you know -- do you know why you'd want to remove and discard a filter and put it into biohazardous waste?

MR. GORDON: Object to the form of the question, and also lack of foundation.

**A. I -- I don't know why. I can only make assumptions.**

Q. Okay. Has 3M ever mentioned or indicated to you that the Bair Hugger units can become contaminated?

**A. I don't recall.**

Q. Now in the e-mail it says, "Remove and discard the filter (in the biohazardous waste).

"Clean the filter retainer and the outside of the unit (including the hose) with full spectrum (quaternary ammonium salt) antiseptic wipe or spray.

"Wipe off all surfaces and install a new filter."

Did I read -- do you see where I read that correctly? Did I read that correctly?

**A. Yeah.**

Q. Okay. Reading this e-mail today, you still have no concern with respect to a Bair Hugger being contaminated and being used in the OR in a surgery?

MR. GORDON: Object to the form of the question.

**A. Reading it, I can see that it's become contaminated. I don't see yet why it should not be**



**used in surgery.**

Q. But they should be cleaned be -- before it's used in surgery again; correct?

MR. GORDON: Object to the form of the question, also lack of foundation.

**A. That particular unit, probably yes.**

Q. Because it's a potential source of contamination in the operating room; correct?

MR. GORDON: Object to the form of the question, also lack of foundation.

MS. DIFRANCO: I'll object, counsel. She's never seen this e-mail before, so to make --

I mean she's a fact witness here to talk about what she knows about this. To make those -- I mean she's not an expert in this case. If --

But go ahead, doctor, if you know the answer to his question.

**A. I actually don't. I don't.**

Q. You agree with me that patient safety is paramount in -- in the practice of medicine; correct?

**A. Absolutely.**

Q. And even you agree with me, as you being an advisory to 3M and other companies that manufacture medical devices, patient safety is paramount; correct?

**A. Correct.**



Q. You don't want to create a device or do anything that may put the patient at harm.

MR. GORDON: Object to the form of the question.

**A. You have never proven to me that a patient is at harm.**

Q. I didn't say prove. I say you yourself would never want to advise a company to create a product or manufacture a product that may put a patient at harm.

MR. GORDON: Object to the form of the question.

MS. DIFRANCO: Go ahead.

**A. Yes, you're correct.**

Q. Okay. And you yourself as an orthopedic surgeon -- or as an anesthesiologist would not use a device in the OR that may cause a patient harm.

MR. GORDON: Object to the form of the question.

Q. Correct?

**A. I would not use a device from which I am convinced that it would cause harm.**

Q. Okay. What evidence do you have -- well strike that.

Based on this e-mail, are you aware that --



and this is a 3M e-mail -- that the Bair Hugger can become contaminated?

**A. Yes.**

Q. You're aware of that; correct?

**A. Correct.**

Q. You heard about it from before; correct?

**A. Yes.**

Q. Okay. What evidence do you have that indicates to you that the Bair Hugger doesn't blow out bacteria onto the patient during use while being used in the OR?

**A. None.**

Q. Okay. Well you're looking for evidence of the opposite, that it actually causes infection, rather than --

**A. Correct.**

Q. -- the evidence that it actually does not cause infection.

**A. Correct.**

Q. Okay. You are aware that there was no validation study of the Bair Hugger before it was put into use --

MR. GORDON: Object to the form --

Q. -- in the -- intraoperatively.

MR. GORDON: Object to the form of the

question.
**A. What is a validation study?**
Q. There was no clinical study done regarding the safety of the Bair Hugger before it was put into use into the market in the United States.
MR. GORDON: Object to the form of the question.
**A. I'm not sure there really wasn't.**
Q. You're aware -- you're aware of clinical studies; correct?
**A. Yes.**
Q. You're aware of 510 -- or 510(k) clearance.
**A. Right.**
Q. Okay. Are you aware that the Bair Hugger unit, the 505, was a 510(k) clearance device?
**A. Yes.**
Q. Okay. So there's no clinical studies that were performed with respect to the 5 -- the 505 unit; correct?
**A. I guess yes, correct.**
Q. Therefore, there's no clinical studies to show that the Bair Hugger was safe for use intraoperatively before it went to the market.
MR. GORDON: Object to the form of the question.



**A. I really don't want to answer that because there's no way to provide that data.**
Q. Well clinical studies indicate that the product is safe; correct?
MR. GORDON: Object to the form of the question.
**A. Clinical studies indicate that the product improves patient outcome.**
Q. And it also looks at the -- the risk factor; correct?
**A. Therefore, it is safe.**
Q. Okay. Therefore, it's safe. And -- and part of the criteria for a clinical study is safety; correct?
**A. Yes.**
Q. Okay. That criteria doesn't exist for a 510(k); correct?
**A. This is correct.**
Q. Okay. Are you aware that the Bair Hugger unit, the 505, the predicate device was a 1937 cast warmer manufactured in the United -- manufactured in the United States?
**A. No.**
MR. GORDON: Object to the form of the question, also lack of foundation.



Q. So when I say a validation study, I'm talking about a clinical study that proves that the -- that -- that -- that shows that the Bair Hugger is -- is effective and safe. Are you aware of any studies that have done that --
MR. GORDON: Same objections.
Q. -- prior to being put into the market?
MR. GORDON: Same objections.
**A. Yeah. I really don't understand where you're going; that's why I have a problem.**
Q. Well you understand what clinical studies are -- are -- are done for; correct?
**A. Yes.**
Q. Okay. If there's no predicate device, then you have to do a clinical study that shows the efficacy and safety of -- of the medical device; correct?
**A. Right.**
Q. None was done for the Bair Hugger; correct?
MR. GORDON: Object to the form of the question, also lack of foundation.
**A. Yeah, an efficacy study was done.**
Q. Huh?
**A. I mean even my own study was an efficacy study.**



Q. But it wasn't a safety study.
**A. No, it was not.**
Q. Okay. Did you have any discussions with Dr. Augustine regarding his allegations regarding the safety of Bair Hugger?
**A. No.**
MR. ASSAAD: Exhibit 229.
(Exhibit 229 handed to the witness.)
THE WITNESS: Thank you.
Q. Exhibit 229 is an e-mail from Dr. Sessler with an attachment for PerfecTemp, PerfecTemp, and attached to it is an article entitled "A Randomized Comparison of Intraoperative PerfecTemp and Forced-Air Warming During Open Abdominal Surgery." Have you seen this article before?
**A. I can't remember.**
Q. Okay. The reason I want to ask you about it is on your CV on page 16, talking about corporate funding, you have listed "LMA-Perfect temperature versus Forced air warming," and I'm wondering if this article is a result of your work even though you're not a named author on this subject matter.
**A. I can't remember. Sorry.**
Q. You don't remember?
**A. I don't.**

Q. You don't remember sitting here today?
**A. Hmm?**
Q. You don't remember.
**A. I don't remember.**
Q. Okay. Are you familiar with the PerfecTemp device?
**A. The PerfecTemp. Was it the LMA, the -- No.**
Q. Okay.
**A. I mean at -- at -- at this second I can't recall it.**
Q. It's a -- it's a conductive --
**A. I can't --**
Q. It's a conductive warming unit that lays on top of the operating room table.
**A. Then I probably am, yes.**
Q. Let me --
**A. No, I -- I -- I probably am. Is it like a mattress?**
Q. Yes. And I'll give you some more in --
**A. Yeah. No, no, I -- I probably am.**
MR. ASSAAD: Mark this.
**A. It's actually in here. I don't --**
MR. ASSAAD: Did I give you two copies?
MS. DIFRANCO: No.



(Exhibit 240 was marked for identification.)
BY MR. ASSAAD:
Q. Exhibit 240 is a document I pulled off the internet entitled "LMA PerfecTemp versus Forced-air Warming."
**A. Uh-huh.**
Q. Department of Outcomes Research at the Cleveland Clinic. I take it that is the department you work for, you're chair of.
**A. No, I'm not.**
Q. Vice chair.
**A. I was, yes.**
Q. Vice chair.
And if you go to the third page, do you see a picture of the device?
**A. Yeah, yeah.**
Q. Do you know this device?
**A. I've probably seen it a few times.**
Q. Okay.
**A. Yes. Yeah.**
Q. This research that was done that you see the -- that -- that they paid $196,000 for, Dr. Sessler was the principal investigator, was that -- does that refresh your recollection of whether



or not that was for this paper that's Exhibit No. 229?
MR. GORDON: Objection, lack of foundation.
**A. I assume it was.**
Q. Have you seen this PowerPoint presentation before?
**A. If the study was done in Outcomes Research, probably. But I can't remember it.**
Q. Did you create this PowerPoint presentation?
**A. No.**
Q. If you go to page 10 -- and I apologize for the poor print job, but the printer at the hotel was not satisfactory.
**A. Yeah.**
Q. It says "Why PerfecTemp?" and the last bullet point says, "It does not blow -- It does not blowing air so it's totally silent with no chance of potential increase risk of contamination." Have you seen that statement before?
**A. I cannot remember it.**
Q. Okay. Do you recall anyone discussing the risk of contamination with blowing air?
**A. In that context, no.**
Q. Is this a document that was created by the Department of Outcomes Research?
MR. GORDON: Objection, lack of foundation.



**A. It looks like it.**
Q. Sitting here today, do you have any reason to believe that this document wasn't created by someone at Outcomes Research?
MR. GORDON: Same objection.
**A. No.**
Q. And as you continue on, it talks about subject selection and the hypothesis --
**A. Uh-huh.**
Q. -- and the protocol. Do you see all that?
**A. Yes, I do.**
Q. Would -- would it be fair to state that this -- this document was created before the study was performed?
MR. GORDON: Object to the form of the question, also lack of foundation.
**A. Most likely, yes.**
Q. And reading through this, do you know -- does it refresh your recollection whether or not you were involved in the protocols -- creation of the protocols for this study?
**A. If so, only very peripherally. Otherwise --**
Q. What do you remember?
**A. The only thing sitting here that I remember is seeing that picture.**

Q. Seeing this picture.
**A. Of the device, yes.**
Q. Okay. Which is on page three.
**A. Yes.**
Q. Okay. Do you remember doing any part of the testing or any part of the writing of the manuscript?
**A. I don't.**
Q. Okay.
**A. And I most likely didn't; otherwise, my name would be on the manuscript.**
Q. Well based on your CV, you were definitely involved with respect to some sort of research done on PerfecTemp.
MR. GORDON: Object to the form of the question.
**A. Hmm?**
Q. Correct?
**A. Not necessarily.**
Q. Well under corporate sources for -- for research that you've done, you put on page 16 "LMA-Perfect temperature versus Forced air warming," so you had some involvement in that research; correct?
**A. I -- I should, I might, but I really don't recall much about that device.**
Q. Let's take it in the negative. Is there



any --
I mean would you agree with me that you would not put anything on your CV indicating research funding that you've obtained that was not research funding you obtained and did work on?
**A. Ideally, yes.**
Q. Okay. So you put this on your CV, so you actually were involved in some sort of research with PerfecTemp; correct?
**A. I must have been, yeah.**
Q. Okay. You're not disagreeing with that statement.
**A. I do not disagree.**
Q. All right. And -- and the research funding was $196,000.
**A. Might have been, yes.**
Q. Well that's what it says on your CV, --
**A. Yes.**
Q. -- so that's correct; correct?
**A. That's correct then.**
Q. Okay. And that's a significant amount of funding; correct?
MR. GORDON: Object to the form of the question.
**A. Depends where you come from. Yes.**



Q. Well --
Have you ever used the PerfecTemp in practice?
**A. No.**
Q. Do you recall any meetings with the -- with LMA, the manufacturer of PerfecTemp?
**A. Not nec --**
**I might have been involved in one or another, but I don't really recall them.**
Q. Do you have any ownership or stock options in any medical-device company?
**A. No.**
Q. Going back a couple --
The use of Mistral by the Cleveland Clinic, have you had any discussions with anyone at 3M with respect to the -- with respect to the Cleveland Clinic using Mistral instead of Bair Hugger?
**A. With the Cleveland Clinic, no.**
Q. But outside the Cleveland Clinic, during any advisory meetings, telephone calls, meetings?
**A. I only recall --**
**I can be much more specific. So we have a personnel department who does all the buying, and she just asked -- advised us about the efficacy, and that was my involvement.**



Q. But after the change --
**A. Oh, after the --**
**Yeah.**
Q. -- did 3M approach you and question why you guys changed from Bair Hugger to Mistral?
**A. Yes, they did.**
Q. And -- and to try to get the Cleveland Clinic back to the Bair Hugger?
**A. So far, very little.**
Q. When they approached you, who approached you?
**A. I don't recall the name exactly. It was Jay -- Jay --**
**I don't know his last name.**
Q. Issa?
**A. Yes.**
Q. And do you recall that conversation?
**A. I do.**
Q. And what -- what was the discussion? What's your -- what's your recollection of the discussion you guys had?
**A. They only wanted to know whether we think that Mistral-Air is -- has the same efficacy as forced-air warming -- as -- as the Bair Hugger --**
Q. Okay.

**A. -- in clinical use.**
Q. And what was your response?
**A. At that point in time it was that I'm unsure.**
Q. And at some point later on you changed your opinion?
**A. Not yet. I'm actually --**
**We are in the process of pulling data to compare the devices.**
Q. But at the time of the changeover, you thought it was as -- as efficacious as the Bair Hugger.
**A. I -- at -- the advice --**
**My advice was it is as efficacious; however, after we've used it for six months, our CRNA thought it wouldn't be.**
Q. Your -- excuse me?
**A. My providers in the room thought it wouldn't be.**
Q. Oh. And their basis was what?
**A. Core temperature at the end of surgery.**
Q. Is there a study being performed between the efficacy of Mistral versus the efficacy of Bair Hugger?
**A. Not yet.**



Q. When you say "not yet," is it -- is it upcoming?
**A. I've had it planned for more than half a year but just didn't get to it. So it should be upcoming.**
Q. Who is sponsoring it?
**A. Nobody. It's a quality-improvement project within our department.**
Q. But sitting here today, there's no evidence that suggests one device is more efficacious than the other.
**A. No.**
Q. Was Dr. Sessler part of the agree -- the discussion with respect to the changeover between the Bair Hugger unit and the Mistral unit?
**A. He was asked about his opinion in regard to efficacy, yes.**
Q. Okay. What was his opinion, do you recall?
**A. Same thing --**
**Actually, very similar to mine, that he also thought it would be as -- it will be very comparable to the Bair Hugger --**
Q. Okay.
**A. -- in regards to heat transfer.**
Q. Let's talk about your favorite subject,



normothermia.
Prior to your 1996 study, was there any evidence that normothermia reduced the incidence of infections?
**A. I don't think that there was a clinical study before that.**
Q. Now my understanding is that you're of the opinion that normothermia reduces -- normothermia during the intraoperative period, maintaining normothermia reduces the risk of wound infection.
**A. Yes.**
Q. Okay. It also reduces the risk of transfusion.
**A. Yes.**
Q. And also -- I'm not sure if this is still your opinion today or not -- reduces the -- the length of stay.
**A. I would have doubts in that regard.**
Q. Okay. So it would be fair to say that the current evidence does -- does not -- the current reli -- the current reliable evidence -- strike that.
There's not enough current reliable evidence to formulate the opinion that maintaining normothermia during the intraoperative period reduces the length of stay for patients.



**A. I would agree, yes.**
Q. Now you corrected me before with respect to hypothermia causes -- we were --
We were talking about the 2015 article in Anesthesia and I said that it reduces bleeding, you said no, reduces the risk of transfusion.
**A. Correct.**
Q. Is there a difference?
**A. The only difference is that bleeding is very difficult to evaluate so there will be a very weak outcome, but of course you are correct, if you need more transfusions, you should bleed more.**
Q. Okay. In the 1960 study -- 1996 study, did you look at bleeding as well, or just --
**A. Not in that particular study.**
Q. Okay. And, of course, one of the benefits of -- of warming a patient is patient comfort.
**A. I would not say "of course," but it should be.**
Q. Okay. Why wouldn't you say "of course?"
**A. I'm not aware that there are lots of studies that really looked at patient comfort.**
Q. So there's no evidence today that maintaining normothermia during the intraoperative period increases patient com -- comfort?

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**A. When? Intraoperative, post -- intraoperative, in their sleep, or --**
Q. Let's talk intraoperatively.
**A. I -- I can't answer that.**
Q. Okay. You can't answer that because there's no evidence and no studies.
**A. No. Because I can't remember it.**
Q. Okay. Okay. So you're aware -- you're aware sitting here today of no studies that looked at that issue.
**A. I'm not aware. I'm almost sure there are some.**
Q. Now are there any other adverse complications that occur with hypothermia that you've looked at besides infection rates and transfusion?
**A. We looked at infection, transfusion, post-operative -- I think we did post-operative recovery, and duration of time in the recovery room. There are studies about drug metabolism, but I think I wasn't involved in any one of those.**
Q. And this is during the intraoperative period; correct?
**A. Yes.**
Q. We're look -- we're looking at the intraoperative period?

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**A. We always look at the intraoperative period.**
Q. All right. And you also looked at length of stay, but the evidence today is not strong.
**A. Length of stay in the recovery room is significant, length of stay in the hospital is questionable.**
Q. Okay. The recovery duration and time in the operating room, what study was that?
**A. That was only part of the '96 paper.**
Q. Okay.
**A. Or in fact, no, there was a second -- a publication from that by Lenhardt about at the same time.**
Q. Okay. Was it the same -- using the same data?
**A. Using same data.**
Q. Okay. So the results are the same in both papers.
**A. I think duration of recovery was not in the first paper at all.**
Q. Okay. It was just length of stay in the first paper.
**A. Uh-huh.**
Q. Okay. And the duration of recovery, that was for colorectal patients.

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**A. Exactly, yes.**
Q. Okay. Are you aware of any study with respect to infection rates and maintaining normothermia besides your 1996 study?
**A. I think there was a repeti -- a second study that was published, --**
Q. The Melling study?
**A. -- the Melling study, thereafter.**
Q. But isn't the Melling study prewarming?
**A. That's a difficult point. Yeah, they -- he did prewarming plus I think intraoperative warming, but it's hard to tell because I think he didn't report core temperatures, so --**
**But it doesn't matter. It -- it's about maintenance of normothermia during surgery because that's what prewarming helps you with as well.**
Q. I understand that. And there's also the new area where, you know --
**A. Which --**
Q. -- you know, pre -- I'll get to it later, but the prewarming for 30 minutes, --
**A. Oh, yeah.**
Q. -- you know, the extremities have a big difference because of Seconal thermodynamics.
**A. Exactly.**

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Q. We'll get to that later.
But my question is: Sitting here today with respect to the Melling article -- and I have a copy of it for you if you want to look at it --
**A. Huh-uh.**
Q. -- where is any evidence that there was any intraoperative warming? Because I heard the same thing at Dr. Sessler's deposition where we read the article --
MR. ASSAAD: Oh, sorry, that's mine. That's your copy.
(Exhibit 241 was marked for identification.)
MR. GORDON: Are you done with your question?
MS. DIFRANCO: Do you want an answer to the question?
MR. ASSAAD: I was marking it and -- Yeah, I'm done with that question.
MR. GORDON: I object to the form of the question.
MS. DIFRANCO: Could you hear his question?
MR. ASSAAD: I'll re -- Let me withdraw the question. I'll restate it.

Q. Exhibit 241 is an article titled "Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomised controlled trial" authored by Andrew Melling, Ba -- Baqar Ali, Eileen Scott and David Leaper.

**A. Uh-huh.**

Q. Are you familiar with this article?

**A. Yes, I am.**

Q. Okay. And we were discussing this article, and it's my understanding that they only looked at prewarming patients and there's no mention of intraoperative warming. Do you agree with that?

MR. GORDON: Object to the form of the question.

**A. I can't remember. I mean I can try to find it here.**

Q. Well let me -- let me backtrack and maybe this will help you remember, And maybe it goes back even further.

You agree with me that intraoperative warming is unnecessary for surgeries that last less than an hour.

**A. I'm not sure.**

Q. Okay. There's no evidence that intraoperative warming is required for surgeries --



or -- or is beneficial for the patient in surgeries that last less than an hour.

**A. Most likely, yeah.**

Q. And even the SCIP protocols, before they were retracted, only required thermal regulation for surgeries lasting longer than an hour.

**A. I know, yeah.**

Q. Okay. If you look at page three of this -- of article Exhibit No. 241, do you see where the length of surgery -- the average length of surgery, they're all less than one hour?

**A. Uh-huh.**

THE REPORTER: Your answer?

Q. Do you see that?

**A. Yes.**

Q. Would that refresh your recollection of whether or not intraoperative warming would have been used during this time period?

**A. No, not at all.**

Q. Okay. Are you aware, back in 2001, whether or not intraoperative warming was the standard of care with regard to surgeries lasting less than an hour?

**A. I'm not. I would assume it was, but I -- I don't know.**

Q. Okay. So do you need some more time to look



at the article to determine whether or not intraoperative warming was used?

**A. Is it relevant?**

Q. It is relevant because we're talking about intraoperative warming in this case and --

**A. No. But is it relevant for your -- for your upcoming questions? Because I cannot figure it out from whatever is written here.**

Q. Well how else would you figure it out if it's not in the article?

**A. You can't.**

Q. Okay. So you can't assume, sitting here today, that intraoperative warming was used in the Melling study; correct?

**A. So poorly written.**

**Yeah, correct.**

Q. Okay. So right now the only article that -- that looked at intraoperative warming and infection rates is your 1996 Kurz article; correct?

**A. Give me one second.**

**Yes, correct.**

Q. My question, from my last question; correct?

**A. Yes.**

Q. Okay. Do you know David Leaper?

**A. No, I don't. Huh-uh.**



Q. And you're aware, if you look at the con -- contributors on ar -- on Exhibit No. 291, Augustine Medical was -- contributed to the -- was acknowledged for its consum -- provision of consumables for the Bair Hugger blankets.

THE REPORTER: It's Exhibit 241.

THE WITNESS: Yes.

MR. ASSAAD: 241, I'm sorry.

**A. Was it?**

Q. Under "Acknowledgments."

**A. "Acknowledgments." Yes.**

Q. And is it fair that Augustine Medical also contributed to your 1996 study?

MR. GORDON: Object -- object to the form of the question.

**A. Most likely, yes.**

Q. But he wasn't involved in any way with respect to the draft of the manuscript.

**A. No.**

Q. Okay. You wouldn't allow that; correct?

**A. No.**

Q. Okay. Now does the degree below core temperature have an effect on the risk of transfusion or the risk of infection?

**A. I assume you mean the depth of hypothermia.**

Q. Yes, the depth of hyp --
**A. Yes, I -- I think so.**
Q. You think so, but there's -- there's no studies at this point with respect to -- withdraw that.
With respect to infections, there are no studies on that issue; correct?
**A. On the specific issue of depth, no.**
Q. Okay. The 2015 article looked at the depth of hypothermia and the risk of -- of transfusion.
**A. Absolutely, yes.**
Q. Okay. In this retrospective study that you're going to be doing that's sponsored by 3M, are you going to be looking at the depth of hypothermia with respect to infection rates?
**A. Yes.**
Q. Okay. Are you -- are you looking at all surgeries, or just colorectal?
**A. I think it's only colorectal.**
Q. Why do you only look at colorectal surgeries?
**A. Because they have the highest incidence of infections after surgery and so you need a smaller number of patients, and secondly, because our colorectal database is the best surgical followup**



**database where we can absolutely rely on the infection data.**
Q. When you say "we," you're talking about the Cleveland Clinic, or are you talking about nationally, globally?
**A. We, the Cleveland Clinic.**
Q. Okay. Colorectal surgeries usually take roughly, on average, about four hours; correct?
**A. Three hours I would expect.**
Q. Three hours now?
**A. Uh-huh.**
Q. I think back in 1996 it was around four hours.
**A. Oh, it was much longer, yeah. And they were all open.**
Q. And all --
And back then in 1996, around that time, a lot of surgeries took a lot longer than they do today.
MR. GORDON: Objection to the form of the question.
**A. Not necessarily.**
Q. All right.
**A. It went down in a very different way.**
Q. For example, hip arthroplasty surgeries were longer back then than they are today.



**A. They were probably longer, but there are -- even today there are large differences where the surgery is done in regards to length, so I -- I don't want to say --**
Q. You don't want to gen --
**A. -- they were longer at that time.**
Q. Is there any other reason why you only look at colorectal as compared to, say, you know, any other type of surgery?
**A. No, there isn't.**
Q. It's -- it's more -- you need a lot more patients looking at other -- to power --
To power a study of a different type of surgery, you would need -- need a lot more patients.
**A. Yes.**
**(Discussion off the stenographic record.)**
**(Exhibit 242 was marked for identification.)**
BY MR. ASSAAD:
Q. What's been marked as Exhibit 242 is an article in the New England Journal of Medicine titled "PERIOPERATIVE NORMOTHERMIA TO REDUCE THE INCIDENCE OF SURGICAL-WOUND INFECTION AND SHORTEN HOSPITALIZATION" dated May 9th, 1996, in which you're the first author.
**A. Yeah.**



Q. You are familiar with this article; correct?
**A. Yes.**
Q. And if you look at the -- the small print in the bottom left-hand corner of the first page, it states, "Supported in grants -- in part by grants from the National Institute of Health, by the Joseph Drown and Max Kade Foundations, and by Augustine Medical Incorporated."
**A. Uh-huh, yes.**
Q. So Augustine, Dr. Augustine, helped fund this study.
MR. GORDON: Object to the form of the question.
**A. Most likely did, yes.**
Q. When you say "Supported in part by grants...," grants would be money; correct?
**A. Absolutely.**
Q. Okay. Who created the protocols for this study?
**A. That was Dan Sessler and me.**
Q. Okay. And this is when you were a fellow; correct?
**A. Exactly.**
Q. Who did the majority of the analysis?
**A. That was also Dan and me.**

Q. Okay. And who did -- who -- who wrote the --

Who wrote most of the manuscript?

**A. I want to say both of us, but he probably wrote a little bit more than I did because he was my senior.**

Q. Okay. And who is Rainer Lenhardt?

**A. He was in -- a colleague at the University of Vienna where this study was conducted.**

Q. And why was the study conducted in the University of Vienna -- Vienna as compared to San Francisco where you were located?

**A. Because this study actually happened --**

**Because Vienna was my home institution, and part of admission when you do a fellowship in another country is to bring knowledge back to your home institution, get them involved in whatever activities you were sent out to learn.**

Q. Uh-huh.

**A. And so --**

**And the second part was that usually the universities, the main campus didn't have a large population as opposed to -- for the patients needed -- needed for this study, and in Vienna we did.**

Q. And -- okay. I have a couple questions.



Actually, I have many questions.

If you look at the first paragraph, you know, where it starts with "Wound...," about two-thirds of the way down it says, "Mild perioperative hypothermity -- hypothermia (approximately two degrees Celsius below the normal core body temperature) is common in colon surgery."

**A. Uh-huh, yes.**

Q. You told me before that mild hypothermia was 35.5 degrees Celsius, but if normal core body temperature is about 36.5, why is mild hypothermia in this case two degrees Celsius below instead of one?

**A. I guess we just called it differently more than 20 years ago, because what is mild -- was considered mild now was, 20 years ago when nobody was warmed in the OR, somewhat different.**

Q. Okay.

**A. So a core temperature of 34 was something we saw every day then, so wasn't a big deal. If we would see it today, we would say it's severe hypothermia.**

Q. Okay. And did you see core temperatures of 34 a lot back then, or was it --

**A. Yes.**

Q. -- 34.5, thirty --

**A. Anywhere. It was rare below --**



**It went down to 33, but 34, 34.5 were very common.**

Q. Okay. So over time that has changed.

**A. Absolutely.**

Q. Okay. Now it's my understanding that in this study you had two groups, a control group and a -- and a group that was warmed with a Bair Hugger unit; correct?

**A. Yes, that's correct.**

Q. And initially you were looking to do this for 400 patients, but after 200 patients you -- you -- you -- you had enough data to get a -- a p-value that was -- that showed statistical significance so you ended the study; correct?

**A. Yes.**

Q. And the control group -- well let me go back.

Before warming was used in the University of Vienna, did they use cotton blankets to keep patients warm?

**A. We have used the oper -- the -- how do you call the --**

Q. Drapes?

**A. Drapes, yeah.**

Q. No blankets, no convective --



**A. No warmed blankets.**

Q. Okay. Okay. In your study, you decided to use the Bair Hugger on for both patients, just had the heating level at a different -- one was ambient and one was heat; correct?

**A. Uh-huh. Yes.**

Q. Why for the control which you decided to use the ambient temperature, which takes basically operating room temperature and pushes it over the patient, instead of just keeping the Bair Hugger off?

**A. We deemed that --**

**You could have done that just as well, but we deemed that the cleaner study design, because our outcome was in many ways also dependent on surgeons, and we wanted to be -- the surgeons -- to have the surgeons and everybody in the OR blinded.**

Q. I understand that. But would you agree with me that taking, you know, anywhere between 18 to 22 degrees Celsius air that's blowing out of a Bair Hugger blanket at the ambient temperature, actually having cooling effect on the patient?

MR. GORDON: Object to the form of the question.

**A. I don't know. Might have.**

Q. Well when you sit in front --

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When you get hot and you put a fan in front of you, don't you feel cooler?
**A. Oh yeah, but I'm not anesthetized I hope.**
Q. Okay. So you think when you're anesthetized, the cooling effect of blowing air is different than when you're not anesthetized?
**A. Absolutely.**
Q. Oh, okay. So you don't think the cooling air that's running over your body is going to take the moisture and -- and bring any type of warmth that's coming from your body away from your body.
**A. That's not what I said. What you say now is correct.**
Q. You're saying that the Bair Hugger blowing at ambient temperature can have a cooling effect on a patient.
**A. It could have, yes, depending on the temp -- the ambient temperature.**
Q. Well what's the ambient temperature of an operating room?
**A. It's in the paper I assume. It should be in the Table 1 --**
Q. Okay.
**A. -- or somewhere I hope.**
Q. 21.9 degrees or 22.1, depending on the -- on

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the control group; correct?
**A. So 22 will not have a large cooling effect.**
Q. Okay.
**A. Nineteen would.**
Q. Nineteen would, but 22 --
And what's your basis behind that?
**A. Oh, there are several studies that show --**
**In fact, there are studies that show when the ambient temperature gets higher than 24 degrees, you don't need a Bair Hugger any more.**
Q. Okay. But we're not at 24 degrees, we're at 22.
**A. Yeah. There are -- I'm --**
**I'm convinced there are volunteer studies that show heat transfer with various different --**
Q. So if your ambient temperature is above 24 degrees, you don't need a Bair Hugger any more according to those studies?
**A. There's one study that showed that, yes.**
Q. Okay. And those studies --
Are you familiar with that study?
**A. Which study?**
Q. The one about being above 24 degrees.
**A. Yes.**
Q. Were the patients having cold air blowing on

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them, or do they have --
**A. No.**
Q. -- blankets on top of them?
**A. Oh, I assume there are blankets on top of them.**
Q. Okay. So they were being warmed with blankets. Okay. So we're kind of looking at apples and oranges, putting cold air above a patient and ambient temperature being 24 degrees.
**A. That's fine, yeah.**
Q. Do you agree?
**A. I do agree.**
Q. Okay. So what other studies do you show that 22 degrees of ambient air blowing over a patient through a Bair Hugger blanket doesn't cause a cooling effect?
**A. I can't recall that now.**
Q. Okay. If you look at the -- at the study, on Table 1 you see the "Final core temperature" for the hypothermic grouping, 34.7 degrees plus or minus .6 degrees; correct?
**A. Wait, wait, I -- I don't have it yet. Where is the core temperature?**
**You're in Table 1.**
Q. Table 1, two-thirds of the way down under

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200 ambient temperature.
**A. Yes.**
Q. I think you're at the wrong --
Keep on going down. I'm looking at "Intraoperative variables," final section.
**A. Oh, yeah. I was thinking -- because mine made no sense here.**
**Yes, got it.**
Q. Okay. Sitting here today, are you aware of -- strike that.
You agree with me that it's a rarity now that patients, whether or not they're using warming or not, get down to 34.7 degrees during surgery.
MR. GORDON: I'll object to the form of the question.
**A. I actually don't agree.**
Q. Do you recall sending an e-mail -- or having a KOL meeting with 3M down in Washington, D.C. and sending an e-mail saying that the -- the hypothermia -- the rates that were used back then is something we rarely see nowadays of thirty --
**A. Yes.**
Q. Okay. What did you mean by that e-mail?
Do you recall stating that?
**A. Oh, it's very simple. That was based on our**

**retrospective study, which only included patients that were warmed.**

Q. By which method, passive warming?

**A. No. All forced-air warming.**

Q. And with respect to -- strike that.

These are surgeries that lasted three hours; correct?

**A. Yes.**

Q. So this is three hours of no warming; correct?

**A. Yes.**

Q. And three hours of air -- Bair Hugger being on blowing ambient air over the patient; correct?

**A. Not correct. It's three hours of active warming with the Bair Hugger at 42 degrees, or three hours of having the Bair Hugger's control with ambient warming.**

Q. Which is just -- which is just ambient air --

**A. Right.**

Q. -- which is at 22 degrees.

**A. Right.**

Q. Okay. And let's correct that one minute. It wasn't at 42 degrees for the -- for the Bair Hugger, it was at 40 degrees; correct?



**A. Yeah. Might have been, yeah.**

Q. Okay. Well if you look at the page before that --

**A. I trust you.**

Q. Okay. Did you look at what the temperatures were at -- strike that.

Under the "Discussion" period, you -- "Discussion" section you write, "The initial hours after bacterial contamination are a decisive period for the establishment of infection." Did I read that correctly?

**A. You --**

**Absolutely.**

Q. What do you mean by that?

**A. That a big --**

**An infection in a patient is usually established during the initial hours of surgery, so it's -- it's not that it happens five days after surgery, it pretty much happens right away, and it's exactly why we give antibiotics before surgery or -- right before surgery and not just in the middle or whenever we think of it.**

Q. So you're saying the -- the -- the -- the contamination occurs during the perioperative period?

**A. Yes.**



Q. Okay. Does that go for all surgeries or just colorectal?

**A. It's different for different surgeries and patient population.**

Q. All right. And then about the next paragraph you write, on the second sentence, "Perioperative hypothermia persisted for more than four hours and thus included the decisive period for establishing an infection."

**A. Correct.**

Q. I'm trying to understand this. Are -- are you saying that you're more susceptible for an infection when you're hypothermic as compared to when you're not hypothermic?

**A. To a certain degree, yes.**

Q. Okay.

**A. Actually, it's exactly what I'm saying.**

Q. Okay. And if I understand you correctly, you're saying because the hypothermia lasted for four hours, because a surgery was three hours plus, that that established enough time for the host defense system to become weakened and therefore unable to fight off a bacteria combination -- con -- contamination, increasing the risk of surgery.

**A. Yes, that's part of it.**



Q. What's the other part?

**A. The other part is that hypothermia causes vasoconstriction, which decreases perfusion to the wound, and therefore nutrients, important nutrients, oxygen and other things that the wound needs for healing, is not getting there.**

Q. At what point does hypothermia cause vasoconstriction?

**A. That depends on the patient's demographic, the anesthetic used, the dose of the anesthetic used. So there are various different factors.**

Q. But if you took best-case scenario, like --

Like what's the highest degree you saw of vasoconstriction below the core temperature?

**A. With a low dose of anesthetic you can get core -- vasoconstriction within a degree.**

Q. One degree?

**A. Yes.**

Q. Okay.

**A. With usually-used doses, you probably tend to go two degrees.**

Q. Two degrees?

**A. (Nodding.)**

Q. Is that a yes?

**A. Yes.**

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Q. Okay. So if a patient is one de -- like at 35 degrees, can you sit here and tell me today what is the risk -- relative risk factor of that patient getting an infection?
**A. No.**
Q. What about at 35 degrees -- or I mean 34 degrees? That would be this study; correct?
**A. Yeah. You could calculate the number needed to treat from that study. I don't know what it is.**
Q. Okay. Does hypothermia --
You mentioned earlier that it depends on your initial core temperature; correct? The delta.
**A. Yes.**
Q. Okay. So, for example, if I am -- have an initial core temperature of -- high, like 37.5, are you going to be seeing the effects at 36.5 because I'm -- I'm a degree below?
**A. We don't know.**
Q. Okay. And the infections you were looking at in this case, they were -- a lot of them were superficial infections; correct?
**A. Yes.**
Q. Okay. None of them dealt with deep infections; correct?
**A. That's not correct. There should have been**

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**deep --**
**We used the CDC criteria for infections. How many were deep I can't remember, or whether any were deep I can't remember. Let's look. What -- where is it? I don't know.**
**Most likely the majority were superficial. Yeah.**
Q. Would you agree with me that of the 200 patients, the ones that got infection, they were mostly superficial infections with few clinical consequences?
**A. I would agree with that, yes.**
Q. Okay. And would you agree with me today that if you -- if you looked at what was considered hypothermia today with colorectal surgery, you're expecting, instead of a three-fold reduction in infections, about 30 percent? That would be your hypothesis?
**A. Yeah, it might be.**
Q. Do you recall informing that to 3M during an advisory meeting?
**A. I don't recall it, but it sounds as something like I could have said.**
MR. ASSAAD: Exhibit No. 218, please.
(Exhibit 218 handed to the witness.)

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BY MR. ASSAAD:
Q. All right. If you look at -- on Exhibit No. 218, take a look at those Bates numbers at the bottom that start with 3M.
**A. Uh-huh.**
Q. If you look at 3M that ends in 445, like three pages on the back side --
**A. Yeah.**
Q. Well let me go back. Let me just explain what this document is. This document was produced by 3M. If you look at the first page, it's dated October 18th, 2012, "Global Patient Warming Advisory Board meeting," and it's the minutes of that meeting.
**A. Uh-huh.**
Q. And you're listed as -- you and Daniel Sessler and a bunch of other people are listed at that meeting.
Do you recall being at that meeting?
**A. Yes, I do.**
Q. Okay. Do you recall discussing the troponin study proposal?
**A. I do.**
Q. Okay. If you look back on the page, it says, "Kurz 1996 SSI paper limitations: only 200 patients, mostly superficial infections with few

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clinical consequences (we should focus on deep tissue/organ SSIs)..."
Did I read that correctly?
**A. Yes, you do.**
Q. It says, "...the factor of 3 risk increase is not plausible (30 or so is -- is more likely)."
**A. Yes.**
Q. Do you agree with that statement?
**A. Absolutely.**
Q. Okay. So are -- are you saying that based on today's knowledge, that if a patient becomes hypothermic, that you're only going to see a 30-percent reduction -- or -- or warming is only going to reduce those patients -- strike that -- maintaining normothermia in colorectal patients will only reduce the infection rate by approximately 30 percent or so?
**A. Absolutely. I would --**
**Yes.**
Q. So what is wrong with the Kurz paper then? Why is -- why is three-fold incorrect today?
**A. It probably is a very small study.**
Q. Okay. And you never looked at deep-tissue infection, just general infections; correct?
**A. No. Deep tissue were looked at. It's only that small sample, there probably weren't many.**

Q. Okay. Do you know how many there were?
**A. No, I don't.**
Q. Is there any way to find out?
**A. I doubt after 20 years.**
Q. Is the data still available?
**A. I doubt it.**
Q. Okay. So if there were any, it would be very few.
**A. Yes, absolutely.**
Q. Okay. If there were any. You're not even sure there were any at all.
**A. I don't.**
Q. Okay. So sitting here today, there is no evidence for you to offer the opinion that maintaining normothermia reduces the incidence of deep-tissue infection.
MR. GORDON: Object to the form of the question, also lack of foundation.
**A. I wouldn't phrase it that way.**
Q. How would you phrase it?
**A. I'm not sure. I'm not --**
**That's one I would have to think about. I don't know.**
Q. Well is there any evidence --
**A. I just don't know.**



Q. Is there any evidence of any research that you've done or read that indicates that maintaining normothermia reduces the incidence of a deep-tissue infection?
**A. I doubt there is, --**
Q. Okay.
**A. -- but I don't know.**
Q. And you agree with me that there's no evidence in the literature that you're aware of that indicates that maintaining normothermia reduces the incidence of a periprosthetic joint infection.
MR. GORDON: Object to the form of the question, also lack of foundation.
**A. So you're saying no -- there's no evidence that normothermia decreases the incidence of --**
Q. Maintaining normo --
Of periprosthetic joint infections.
MS. DIFRANCO: Are you asking what she's done or --
I mean you're getting into some expert testimony here.
MR. ASSAAD: Well I'm not, and I --
If you want me to lay more foundation, I will -- I can. Fine, I'll lay foundation.
Q. You advised for 3M; correct?



**A. Yes.**
Q. They use the Bair Hugger; correct?
**A. Yes.**
Q. They promote the Bair Hugger in orthopedic surgery; correct?
**A. Yeah.**
Q. Okay. Have you ever told them that there's no evidence that 3M --
Or have you ever told them that there's evidence that maintaining normothermia reduces the incidence of periprosthetic joint infection?
**A. No.**
Q. Have you ever informed them that there is no evidence that periprosthetic -- maintaining normothermia reduces the incidence of periprosthetic joint infection?
**A. Yes.**
Q. You have told them that?
**A. Yeah, of course. My paper says at the end that -- or it should say that every -- every patient --**
**Advice always only applies to the patient population tested.**
Q. I understand that. But you --
**A. I can't advise anybody that it would work in**



**eye surgery now or in orthopedic. I don't know.**
Q. Well what can you advise people then, that it only works in colorectal?
**A. Strictly spoken, yes.**
Q. Okay. But you're --
**A. For that indication.**
Q. For what indication?
**A. Infection.**
Q. Okay.
**A. Might be different for other indications.**
Q. Okay. Let's talk about infection. So you've never --
Have you ever advised 3M that there's no study that supports -- or that -- that you can advise them that forced-air warming and maintaining normo -- to maintain normothermia is required for periprosthetic -- or for orthopedic surgeries to reduce periprosthetic joint infection?
**A. Your question is complicated. So I have not --**
**Yeah, it's hard for me to understand the question. I think I didn't advise them to specifically use it for decrease in periprosthetic infections.**
Q. Okay. You're aware that Bair Hugger -- or

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3M and Arizant have marketed the Bair Hugger for all surgeries --
**A. Yes.**
Q. -- that last longer than an hour.
**A. Yes.**
Q. Okay. And you're on the advisory panel for them; correct?
**A. Uh-huh, yes.**
Q. And so is Dr. Sessler, for a longer time than you have.
**A. Yes.**
Q. Okay. And are you saying, sitting here today, that the only advice that you could give is that -- that -- that maintaining normothermia in colorectal surgeries reduces the incidence of infection?
**A. That's the scientific advice.**
Q. Okay.
**A. My clinical interpretation might be slightly different.**
Q. How is it different?
**A. It's that -- that if it does help in a certain patient population, it might -- it's also not proven -- do the same thing in others, and I guess that's why --**

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Q. It may.
**A. It may.**
Q. And it may not.
**A. I don't know.**
**And it may not.**
Q. Okay. And unless you -- and --
And sitting here today, you don't understand the host defense of a -- a -- a -- an individual that has -- that has bacteria that lands on an implant during a total knee or total hip arthroplasty; correct?
**A. That is correct.**
MR. GORDON: Object to the form of the question.
Q. All right. Sitting here today, do you know whether or not hypothermia has any impact on the host defense of an individual that -- that's implant was contaminated during the perioperative period with bacteria?
**A. I don't know.**
Q. You've gone around the world promoting maintaining normothermia; correct?
**A. Yes.**
Q. You've gone around the world saying that all patients should be warmed.

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**A. Yes, I did.**
Q. Okay. And you're basing it off this one study that was done in 1996; correct?
**A. No.**
Q. What else are you basing it on?
**A. Not correct. We based it off on two -- or some studies that looked at blood loss and transfusion requirements back then. We based it off on a study that showed decreased myocardial injury, although a very weak study --**
Q. Is that the Frank study?
**A. That was the Frank study.**
**So actually, I'm not basing it on this any more, but we used to. We base it off on studies that show that drugs are metabolized differently with hypothermia. So it's not only one study --**
Q. Okay.
**A. -- we base this on.**
Q. But with respect to reducing infections --
**A. That's the only study we have.**
Q. Okay. And you also looked at length of stay in this -- in this -- in -- in this article; correct?
**A. In this particular study, yes.**
Q. Okay. And after, I guess, other -- one came in -- in 19 -- in 2006. So after 19 years, the

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information has changed and now you cannot say from a scientific statistical significance that maintaining normothermia has any effect on the length of stay in the hospital.
**A. No. But it's all the very different conditions. So the first study, first of all, patients were in the hospital forever, so it's easy to see a difference. If you look at the duration of hospitalization, I think it was 12 or 14 days 25 years ago, and now it's five days, so it's much harder to show a difference even with hundred times as many patients. And what you actually do see in the retrospective study is that if the temperature gets low enough, it starts to have a difference, which actually is -- doesn't contradict what we said before.**
Q. What do you mean when you look if the temperature gets low enough?
**A. While in the retrospective -- and the other --**
**The large thing is, of course, that retrospective studies only show an association and never a causal relationship. So which study is stronger, which weaker, is -- is to be discussed. If you look at the --**
**I don't have the retrospective one in front**

**of me, but we looked, as you mentioned before, at depth and duration, and if you get very deep and long, I think you would see a -- a -- a relationship which is core temperatures, which we nowadays don't see any more, but we used to see many years ago.**

**(Discussion off the stenographic record.)**

**(Exhibit 243 was marked for identification.)**

**A. Let's see. Should be all the way back.**

**So you have a graph on Bate page 283. So where you have the two probabilities --**

**I guess the left-hand side is the transfusion data. Is that correct?**

Q. Yes.

**A. And the right-hand side should be duration of hospitalization. So you do see that both -- the -- the curves are quite similar, they just happen at different temperature ranges. So if you would get low enough with this one, with the right one, which is something we don't see that commonly any more, you would probably see an effect.**

Q. Well for example, let -- let's take a surgery of two hours. Not a colorectal, but a two-hour surgery.

**A. Uh-huh.**



Q. I mean what -- what do you usually see for degree hours on -- on a --

**A. Nowadays?**

Q. Yeah.

**A. One degree. Time --**

**I'm not sure what the time-weighted average would be. Not much.**

Q. Uh-huh. Probably --

**A. Not much.**

Q. It wouldn't increase the length of stay or transfusion rates. I mean it wouldn't increase the transfusion rates.

**A. Nowadays, I don't think so.**

Q. Okay. Going to page 282, first main paragraph, it states, "Intraoperative forced air did not prevent redistribution hypothermia, which is consistent with previous reports."

**A. Correct.**

Q. And my understanding is the redistribution hypothermia is when your heat goes from your core to your extremities; correct?

**A. Right.**

Q. And that's why prewarming you consider very important to -- to negate that.

**A. I don't consider it very important, but**



**it --**

**To negate that, yes.**

Q. Okay.

**A. Sorry. Yes.**

Q. Okay. And even here it says, "In contrast, it is well established that prewarming reduces redistribution hypothermia by warming peripheral tissues to nearly core temperature."

**A. Correct.**

Q. "Without thermal gradient, the second Law of Thermodynamics specifies that there can be no flow of heat -- and thus no redistribution hypothermia."

**A. Uh-huh.**

Q. Correct?

**A. Yes.**

Q. Okay. And just going back, that's kind of what Mercury Biomed is trying to do in a way.

**A. Yeah. Not only pre --**

**Yes.**

Q. Uh-huh.

**A. A little bit, yes.**

Q. And also to increase vasoconstriction so you could have the heat flow and create heat from the extremities and can bring it back to the core.

**A. Yes, exactly.**



Q. And is it true that even with warming, any type of warming, that a patient still becomes hypothermic within the first hour of surgery?

**A. Yes. Still is some redistribution hypothermia, it's correct.**

Q. Okay. Unless there's prewarming.

**A. Even with prewarming. Then it's minimal. Yes.**

Q. Okay. And is the same -- is -- is the --

Is the curve the same, with regard to the drop in core temperature in the first hour, the same whether or not the patient is -- is warmed?

**A. Intraoperatively.**

Q. Yes.

**A. Yes.**

**Actually, I don't know quite, because usually we only start warming intraoperatively after redistribution hypothermia has happened.**

Q. Which is after the anesthesia is given.

**A. Which -- which is after induction of anesthesia.**

Q. Okay.

**A. Yeah.**

Q. So --

But in patients that are not warmed, have

you looked at -- at -- at their drop in -- in -- in core temperature over --

**A. Yeah, it's about .6 to 1 degree, yes.**

Q. Okay. So the first hour.

**A. About, yeah.**

Q. Okay. And the difference, my understanding is when you have warming, the core temperature begins to increase, and if you have no warming, it continues to decrease.

**A. Until it plateaus, yes.**

Q. So about 34.5 degrees, give or take the type of patient.

**A. Uh-huh.**

Q. Okay. Yes?

**A. Yes.**

Q. Okay. So if a surgery is lasting one hour or less, would you agree with me that maintaining normothermia has no effect on the incidence of infection?

**A. No. I don't think --**

**I think I don't agree with your phrasing because you --**

Q. Let -- let me --

**A. -- you can't not maintain normothermia.**

Q. Okay. Okay. You're right. It was a --



Would you agree with me that within -- within the first hour of a surgery, patient warming has no effect on the incidence of infection, based on your research?

MR. GORDON: Object to the form of the question.

**A. We have not studied that, so I cannot agree.**

Q. Okay. But you agree with me whether or not a patient is warmed or not, their temperature drops, they become hypothermic in their first hour.

**A. To a certain degree, yes.**

Q. And is there any research with respect to the incidence of infection with respect to surgeries that last one hour or less?

**A. I don't know of any.**

Q. What about two hours or less?

**A. I don't know of that either.**

Q. Okay.

**A. There is very little research in that regards, especially prospective research. There might be one or the other retrospective study.**

Q. Going to page 284, I'm looking at Table No. 4, and explain Table No. 4.

MR. GORDON: Object to the form of the question.



**A. I'm not quite a statistician, but I can try.**

**So I think in the left-hand column you have the area under the curve below 37 degrees core temperature in what we explained before, degrees times hour, and what you see, that the adjusted odds ratio to receive an intraoperative transfusion with increased area under 37 significantly increases, so it almost doubles from 1.34 to 2.02, so it is a very, very strong effect. So the deeper and the longer the hypothermia, the more transfusions.**

Q. And we don't have to talk about the duration of hospitalization because that's statistically insignificant; correct?

**A. Right.**

Q. Let me ask you a question. The reference to 36 degrees as a reference point as --

**A. I think we used 37 here.**

Q. Well it's average under -- area under 37 in degree hours.

**A. Yeah.**

Q. So to get to the reference of where it's under one, that's --

**A. Thirty-six.**

Q. -- 36 degrees.

**A. Yeah.**



Q. Why, when you're at thirty -- like .25 degree hours, okay, is your risk higher than 36 degrees when you're not hypothermic for a transfusion?

**A. It's not higher. It's almost a linear decrease.**

Q. But it's saying that if I have .25 degree hours, my odds ratio is 1.34.

**A. Oh, why it's --**

**I don't know. It should actually be going --**

**Wait. No. Because it's -- it's probably a U-shaped curve.**

Q. The odds ratio is a U -- U-shaped --

**A. Not the odds ratio, but the way -- the way you would --**

**See, your reference is one, --**

Q. Okay.

**A. -- so some of those are at higher temperatures versus lower.**

**I would have to read the text for this.**

Q. Okay.

**A. If you want me to do that, I can.**

Q. If -- if you don't know --

I was kind of confused about it because it -- it seems that if you are above 36 degrees for a

shorter period of time, you have a higher risk of a transfusion, which doesn't make any sense.

**A. No, it doesn't. And that's why I think if you are at the higher temp -- so you're at the lower temperature --**

**I need to think about it, --**

Q. Okay.

**A. -- obviously. But you're right.**

Q. So -- so in your experience doing total knee and total hip implant surgeries, how long do they usually last for?

**A. Here at the clinic, two and a half to three hours outside.**

Q. For hip or knee, for both?

**A. I would say for almost both. Hip would be longer. I think in the real world they last about half an hour, 45 minutes.**

Q. Why do they last longer here?

**A. Because we are a teaching institution.**

Q. Okay. All right.

MR. ASSAAD: Want to take a break? I think this is a good time for a break.

THE REPORTER: Off the record, please.

(Recess taken.)

BY MS. DIFRANCO:



Q. Ready to continue?

**A. Yes.**

Q. Do you have --

You have -- you have no expertise in -- with respect to the types of ventilation used in an OR; correct? Things like laminar, unidirectional or conventional?

**A. Oh, sorry. No, no.**

Q. Okay. Are you familiar with the Daniel Sessler article of 2011, which he did a study in respect to particle counts and laminar flow?

**A. I'm not.**

Q. Okay. Did you ever have any discussions with him about that study?

**A. No.**

Q. Okay. Were you aware that he -- he did a study for a favor for 3M -- or authored a study as a favor for 3M back in 2011 that was published?

**A. I don't think so.**

Q. Okay.

**A. I -- I also don't think I was part of it.**

Q. I -- I understand you were not part of that.

**A. Yeah. Yeah. No, no.**

Q. I mean you do -- you do work together a lot; correct?



**A. We do work together a lot, but not on -- not exactly all topics.**

Q. Okay. Are you aware of any comments by the CDC with respect to blowing air -- devices that blow air in the operating room?

**A. No, I'm not.**

Q. Okay. Are you familiar with any issues with --

Do you know what a heater/cooler unit is that's used in cardiac surgery?

**A. I assume it's something that can heat and cool.**

Q. Yeah. Are you familiar with that device?

**A. Not with that specific one, but I've seen it before.**

Q. Are you familiar with the issues with the Sorin heater/cool unit and the causing of infections in the operating room?

**A. No.**

Q. Now it's -- it's my understanding that, based on lectures that I've seen that you did that are on YouTube, that the modality of -- of which way a patient is warmed is insignificant to you, which -- which -- which -- what -- whatever convention it uses; correct?



**A. Yes.**

Q. And based on research that I've read, you agree with me that conductive warming using maybe resistive polymers is just as effective as forced-air warming.

**A. I think I would agree, yes.**

Q. You think you would agree or would you agree?

**A. I agree. Sorry, I was thinking further. I -- I agree in regards to efficiency.**

Q. What do you mean by "efficiency?"

**A. So I think heat transfer is similar. Cost for most of these devices is higher.**

Q. Cost. Okay.

(Exhibit 244 was marked for identification.)

BY MR. ASSAAD:

Q. Dr. Kurz, what's been marked as Exhibit 244 is a publication in Anesthesia & Analgesia titled "Resistive-Polymer Versus Forced-Air Warming: Comparable Efficacy in Orthopedic Patients." Are you familiar with this article?

**A. I am.**

Q. And -- and you are a named author in this article; correct?

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**A. Yes, I am.**
Q. Okay. What was your contribution to this article?
**A. I'm just thinking. I think at that point in time I was the chair of the Department of Anesthesia at this -- and this is a group of my fellows who did this study, so I probably corrected and had input in the methods.**
Q. And -- and you agree with the result of this study?
**A. Yeah. If my name is on there, yes.**
Q. Okay. I just want to go over certain parts of -- that's written in this. And you -- have you -- strike that.
Did you have the opportunity to edit this study before it went to publication?
**A. I'm sure I did.**
Q. Okay. And in two thousand -- this is published in 2010. During the time -- and it was accepted for publication on November 8th, 2009.
At the time that this study came out, were you on the advisory board for 3M?
**A. I don't know.**
Q. All right. Going to the first paragraph, about the second or third sentence down, it starts,

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"Even mild hypothermia..." Do you see that?
**A. Second sentence --**
Q. Seventh line down.
**A. "Even mild hypothermia..." Yes.**
Q. Says, "Even mild hypothermia triples the incidence of post-operative wound infection and increases the hospital length of stay" --
**A. Uh-huh.**
Q. -- "by 20 percent, increases blood loss and blood transfusion requirements, and increases the incidence of cardiovascular complications and thermo discomfort of patients."
Did I read that correctly?
**A. Yes, you did.**
Q. Sitting here today, would I be correct that you disagree -- or your hypothesis is different with respect to hypothermia reducing the incidence of post-operative infection by -- or -- or triples the incidence of post-operative wound infection?
**A. The statement is correct.**
Q. I understand that. But basing what --
**A. Whether the effect size is the same, I doubt.**
Q. What do you mean the --
**A. So it's exactly what you said before. The**

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**triple is correct for that particular paper or what we cite here. Whether the effect size is the same nowadays, I don't know.**
Q. But would you agree with me that, as you stated previously, the third -- the triple -- the reduction by three times only applies to colorectal surgery, that that's where the evidence is; correct?
**A. Absolutely.**
MR. GORDON: Object.
Q. But it doesn't say that here; does it?
**A. No, but it cites the paper.**
Q. I understand that. But a person reading this, wouldn't he be misled that this applies to all surgeries?
MR. GORDON: Object to the form of the question, lack of foundation.
**A. I don't know.**
Q. Okay. I mean it doesn't say anywhere here colorectal surgery; correct?
**A. No, it does not.**
Q. Okay. And in fact, nothing in this paragraph, with all this data, applies to the type of surgery that there's evidence that these statements support; correct?
**A. Oh, absolutely it does. It's the first --**

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**The first part applies to colorectal, the second part to orthopedic, last part I cannot remember.**
Q. And the orthopedic reference is, I think, Schmid or --
**A. It's Schmid and --**
Q. Hertz -- Kurz.
**A. No, no, I wasn't the first author on any of those. It's Schmid, and there's a second one in orthopedic, Visna or -- ba ba ba ba.**
**Schmid. I guess they only had Schmid at that time, yeah.**
Q. And that -- that's an article in The Lancet published in 1996; correct?
**A. Correct.**
Q. And actually, you put that down in -- in your CV as a separate category of publications, "High Profile Articles;" correct?
**A. Correct.**
Q. Okay. Along with the 1996 study of --
**A. Correct.**
Q. Okay. So you considered those articles were high-profile articles.
**A. Absolutely I do.**
Q. Okay. And with respect to the increase of

the hospital length of stay by 20 percent, as we discussed previously, based on recent studies, that's questionable.

**A. Yes, it is.**

Q. Okay. And increased blood loss and blood transfusion requirements, we no long want -- we no want -- longer want to look at blood loss because that's not -- the data is not that accurate as compared to blood transfusions.

**A. Yes.**

Q. Okay.

**A. Al -- although for these particular prospective studies, blood loss is evaluated differently than for retrospective studies. So that's why I said that it's unreliable for retrospective studies but not so much for prospective.**

Q. And with all these studies regarding blood loss, length of stay, transfusions, infections, the depth of hypothermia is unknown to -- with -- with respect to the effect that the depth of hypothermia would have on -- on these complications.

**A. No, that's incorrect. For all these studies, the depth was very well known. They all went down to around 34.4 degrees, so they all had a very large area under the curve.**



Q. Okay. So a patient that can be warmed with blankets, that's at 35 degrees, 35 point -- between 35 and 35 degrees without active warming, we don't know what the effect of hypothermia would have on those patients with respect to infection rates, blood loss, blood transfusions, length of stay.

**A. So you are asking whether a patient who has a higher core temperature than 34.5 degrees would have a different infection rate or fewer infections.**

Q. If any.

**A. I --**

**We don't know.**

Q. Okay.

**A. In fact, we don't know for infection. We do know for blood -- blood loss.**

Q. You're correct, because of the degree hours.

**A. Yeah.**

Q. Okay.

**A. No. Because of a second study that was done with very, very mild hypothermia in around this time period.**

Q. And what sur -- what type of surgeries was that?

**A. Orthopedic.**

Q. Okay.



**A. It's the one I was looking for in here, but --**

Q. Okay. What type of -- what type of orthopedic surgeries?

**A. Hip.**

Q. Okay. And was that around 1996?

**A. Yes.**

Q. Okay. Has hip arthroplasty changed over the past 20 years, the way the surgery is done?

**A. You know what? I'm an anesthesiologist. I guess it has.**

Q. Okay. So you don't know one way or the other.

**A. No.**

Q. Okay. So sitting here today, you don't know if -- if the procedure or the mechanism or -- or the way they do the surgery is different in 2016 as it was in 1996.

**A. I would hope it's different.**

Q. Okay. And in fact, the number of hip arthroplasties and knee arthroplasties have increased significantly over the past 20 years per year.

**A. I agree, yeah.**

Q. You write here that the resistive -- on the -- on the second paragraph, "This system might



have" -- talking about --

**A. Uh-huh.**

Q. -- resistive polymers -- "This system might have some advantages compared with a forced-air warming system: blankets are reusable, there is no air flow and thus warming can be initiated immediately after induction with anesthesia without waiting for surgical draping to be completed..." Did I read that correctly?

**A. Yes, you do.**

Q. So is it my understanding that an advantage of a resistive-polymer or conductive blanket is that you could begin warming the patient sooner than with forced-air warming?

**A. That's correct, yeah.**

Q. And that's better for the patient.

**A. I would assume.**

Q. Okay. "...and its operation is silent." Why is that an advantage?

**A. Because noise in the operating room distracts.**

Q. Distracts the surgeons?

**A. Or the anesthesiologist, whoever is working there.**

Q. Or the nurse anesthetist.

Going to the next page, the paragraph says, "Before induction of anesthesia, patients were randomly assigned, using a computer-generated randomization sequence in which the group assignment was kept in sequence -- sequentially numbered opaque envelope, to 1 of 2 treatments: (1) Forced-Air warming with the Bair Hugger upper body warming cover (model 525) connected to a model 750 warming unit set to 'high' (at 43 degrees Celsius); or (2) resistive-polymer warming (RP group) with 2 Hot Dog warming blankets (model: Multiposition Blanket) and the Hot Dog control unit set to 'high' (at 43 degrees Celsius)."

Did I read that correctly?

**A. Yes, you do.**

MR. GORDON: Actually it's 522, not 525.

MR. ASSAAD: Oh, I'm sorry. 522. Thank you counselor.

Q. So it's my understanding that the control -- there are two groups, one that used the Bair Hugger 750 model and the other one used the Hot Dog warming device.

**A. Correct.**

Q. Were you present for any of the testing?

**A. I can't remember, but I would assume so.**



Q. Okay. And it's my understanding, if you look at the next column, "The core warming rate (degree Celsius over hours) was calculated from a starting point 30 minutes after induction of anesthesia to the end of surgery..."

So you took data for that period of the core -- core temperature.

**A. Yes.**

Q. Okay. And you recorded temperatures every five minutes until the end of surgery.

**A. Correct.**

Q. Okay. And you also took the environmental temperature close to the patient, approximately one meter distance and in the OR. Do you see that? It's about the --

**A. Yeah, I see that.**

Q. Why was that done?

**A. Good question. I can't remember.**

Q. Do you remember it being done?

**A. No, I don't, but it's for sure done if it's here. Maybe there --**

**Is there anything in the discussion that explains it?**

Q. Yeah, we'll get -- we'll get to it in a second.



When it says "approximately one meter distance," do you know what they're referring to?

**A. I would assume the area where the anesthesiologist is placed.**

Q. Okay. One meter from there.

**A. One meter --**

**Oh, sorry. "...patients...one meter distance...environment temperature close to the... approximately one meter distance." No, one me --**

**I would assume one meter distance from the patient's head, which is our access, which is where we are.**

Q. One -- one meter down or one meter up or --

**A. No. One meter in our --**

Q. Towards the anesthesiologist?

**A. Good question. I don't know.**

Q. Okay. Well if you -- if you --

If going through this reminds you, please let me know. Okay?

**A. Yes.**

Q. Under the "Statistical Analysis" it -- it states that "A sample size of 80 patients was estimated to achieve a power of 90 percent to detect equivalence within the specified equivalence bounds." Did I read that correctly?



**A. Yes, you do.**

Q. So a calculation was made, and to get a meaningful result you needed 80 -- 80 patients.

**A. Yes.**

Q. Okay. And under the "RESULTS" under your study it states that "There were no differences in demographic and morphometric characteristics, except for gender with more female patients in the FA group."

**A. Okay.**

Q. Did I read that correctly?

**A. Yes.**

Q. Okay. Having more female patients than male patients, would that make -- would that have any -- would that have any effect on core body temperature results?

**A. Very little under anesthesia.**

Q. Okay. It says, next paragraph, "After induction of anesthesia, core temperature decreased similarly for a period of approximately 30 minutes in both groups. Subsequently, core temperature increased at comparable rates in both groups (.33 degrees Celsius per hour plus or minus .34 degrees Celsius per hour and .29 degrees Celsius per hour plus or minus .35 degrees Celsius per hour for groups forced-air warming and resistive polymer, respectively..."

Based on that statement, is it correct that there was no -- there was very little or no difference between the Hot Dog and the Bair Hugger units?

**A. That's correct.**

Q. Okay. "There were also no differences between the 2 groups in the course of core temperature, mean body temperature, and mean skin temperature..." Is that a correct statement?

**A. Yes, it is.**

Q. Okay. So basically what it's saying is that -- basically that they were almost identical.

**A. Yeah. Yes.**

Q. Okay.

**A. Uh-huh.**

Q. And it goes on, "We did not find significant intra -- intragroup core temperature differences between patients with esophageal and bladder core temperature probes (results not shown)."

Is that -- is that the norm?

**A. That's what you would expect. That's --**

Q. Okay. And it also goes on, the next paragraph, "No patient in this study needed postoperative warming in the recovery room. Thirty minutes after admission to the postanesthesia recovery room, the patients' thermal comfort was not different



between forced-air warming and resistive polymer..." Did I read that correctly?

**A. Yes.**

Q. And how do you measure thermal comfort using a VAS?

**A. I assume we used a VAS. Yeah.**

Q. What is a VAS?

**A. A visual analyst's score. So you base --**

Q. It's objective?

**A. It's objective. We look at --**

Q. Okay. Next paragraph, which I want to get to, says, "The room temperature and the environmental temperature (close proximity to the patient) were not different at induction of anesthesia between forced-air warming and resistive-polymer groups. In contrast, the environmental temperature in close proximity to the workplace of the surgical and anesthesia team increased more with forced-air patient warmer (at 24.4 degrees C plus or minus 5.2 degrees Celsius for forced-air warming versus 22.6 degrees Celsius plus or minus 1.9 degrees Celsius for resistive polymer at 30 minutes..." with a p-value of .01. Did I read that correctly?

**A. Yes.**

Q. Okay. So is it correct that my



understanding is that the forced-air warming increased the temperature around the surgical team and the anesthesia team more than the conductive warming?

**A. Correct.**

Q. Would you agree with me that it's --

Is that because the waste heat that's coming out of the forced-air warming is more than coming out of the conductive warming?

**A. I wouldn't call it waste heat, but yes.**

**I -- I guess it's mainly that whatever you get out of a convective system distributes very differently as opposed to from a conductive system.**

Q. And it causes more heat around the operating room table.

**A. Yes.**

Q. Okay. That's what this study states pretty much; correct?

**A. That's what it says, yes.**

Q. Okay. And is that something that you were aware of before using forced-air warming?

**A. Yes.**

Q. And how were you aware of it?

**A. Just by surgeons and nurses complaining that it's warm.**

Q. So -- so surgeons and nurses complained to



you that when they used forced-air warming, it was warm around the operating room table?

**A. Yes.**

Q. Approximately how many times?

**A. I can't tell. It doesn't -- it doesn't --**

Q. Dozens, hundreds?

**A. Not hundreds. I would say dozens --**

Q. Okay.

**A. -- over 20 years.**

Q. Under the "DISCUSSION," about 15 lines down, it says, "Some intrinsic limitations of FA..." Do you see that?

**A. Yes, I see.**

Q. It says, "Some intrinsic limitations of forced-air warmers include the expense of using disposable blankets for each patient; the noise of the fan; and the increased OR temperature in the proximity of the device, resulting in thermal discomfort of the surgical staff." Did I read that correctly?

**A. Yes.**

Q. Do you agree with that statement?

**A. Yes, I do.**

Q. Okay. So -- so the expense of using disposable blankets is a limitation of using the Bair Hugger model.

**A. It's always more expensive, yes.**
Q. Than using conductive warming?
**A. No, than using non-disposable devices.**
Q. Okay. "Other concerns include the potential contamination of the parts of the forced-air warming device (the hose and blower) with bacterial pathogens" --
Do you agree with that statement?
**A. I guess. Otherwise, we would not have put it here.**
Q. Okay.
-- "which could be transferred by the airstream to the surgical field and cause infections." Do you agree with that statement?
**A. To a certain extent, yes.**
Q. You did not edit that statement out or have any disagreement by putting your name --
**A. When I --**
**No.**
Q. Okay. And I assume as an author such as yourself, and a scientist, that if you specifically disagreed with a conclusion or a statement in an article, that you would not allow it to be put under your name.
**A. You're absolutely correct. That's why it**



**has the followup sentence here.**
Q. I -- I understand that. "However, several studies challenged the clinical relevance of these results and found no difference in bacterial dispersion with or without forced-air warming -- forced air;" correct?
**A. Correct.**
Q. Okay. Will you agree with me that it was an issue with respect to the limitations of forced-air warming that you addressed in this paper?
**A. It was an issue we addressed in the "DISCUSSION." We did not address it in the paper because we didn't study it.**
Q. But you address it in "DISCUSSION."
**A. Right.**
Q. On the next paragraph it states, "The new warming device (Hot Dog) uses a different technology, resistive warming of a polymer blanket. Potential advantages of resistive warming compared with forced-air warming include the following: all parts of the system are reusable, thereby reducing costs and the environmental burden..." Do you agree with that statement?
**A. I agree.**
Q. So by the fact that the -- that the



conductive blankets are reusable, it reduces cost.
**A. Yes, I think it does.**
Q. Okay.
**A. Or it was true at that given point in time.**
Q. In -- in 2009, 2010.
**A. Yeah.**
Q. Okay. Has the price of Bair Huggers gone down, blankets, since 2010?
**A. I believe they've gone down considerably over the past 20 years. When exactly the changes were, I don't know.**
Q. Okay. So you don't know what the difference was, the price of a Bair Hugger blanket, in 2010 as compared to --
**A. No.**
Q. -- 2016.
**A. No, I do not.**
Q. Okay. Next statement, "...there is possibly less warming of the OR environment, resulting in increased thermal comfort for OR staff..." Do you agree with that statement?
**A. Yes, I do.**
Q. Okay. Finally it says, "...and cleaning and disinfection are relatively easy, thus decreasing the risk of colonization with pathogens." Do you agree



with that statement?
**A. I did at that point in time. I actually don't any more.**
Q. What caused you to change your opinion?
**A. That it turns out that cleaning and disinfecting any reusable device is -- is more difficult and costly than we would have ever thought.**
Q. Okay. Based on work -- work staff?
**A. Yeah.**
Q. Okay.
**A. And I'm not sure whether it was or was not at that time, --**
Q. Okay.
**A. -- but I'm not --**
**Nowadays, I wouldn't completely agree with that.**
Q. So you don't know what the cost was back then.
**A. No, I don't. I don't.**
Q. Okay. It could have been the same cost it is now, you're just not aware.
**A. Yes.**
Q. Okay. Do you know what the cost of -- of cleaning a -- a Bair Hugger unit is?
**A. No, I don't.**

Q. Okay. On the next column -- or next --
The next column, first full paragraph says, "Our study demonstrates that intraoperative warming with the -- with the resistive-polymer system was as effective as warming with the forced air system." You agree with that; correct?
**A. Yes, I do.**
Q. And then you continue on talking about the other studies that indicated that the resistive heating pad system was inferior to forced-air warming in the paragraph below that. Do you see that?
**A. Yes, I do.**
Q. Are you familiar with those studies, Russell and Freeman?
**A. Russell and Freeman I can't remember.**
Q. What about Leung et al?
**A. Leung et al. You know, I can't remember. I'm -- I'm sure I knew them at some point, but I can't remember now.**
Q. Regardless of whether -- I'm sorry.
Regardless of whether or not you remember them today, would you agree with me that the discussion point in this paragraph you would agree -- you agreed with at the time of the publication?
**A. I would say yes.**



Q. Okay. Do you agree that Russell and Freeman had a limitation, that they used different temperature settings for the heating pad as compared to the forced-air warming? Do you agree with that statement?
**A. I don't know. I mean if it's -- if it's here, I must have agreed, --**
Q. Okay.
**A. -- but I don't know today.**
Q. Okay. But today you have no reason to disagree with -- with those statements.
**A. No, I don't.**
Q. Okay. The final paragraph, it says on that paragraph, "Interestingly, the OR temperature close to the patient increased significantly at 30 minutes, corresponding to the end of surgery in the first forced-air warming group patient. Although this may have resulted in decreased OR staff members' comfort, we did not measure thermal comfort levels in this study."
So you didn't measure the patient thermal comfort levels at all.
**A. No.**
Q. Okay. And just to be clear, I'd like to go to the graph -- or the table on page three, and I just want to make sure I understand it right and the ladies and gentlemen of the jury understand it right. If you -- if you go to environmental temperature at one meter distance to the warming device --



**A. Which -- which -- which one is it?**
Q. -- after 30 minutes --
**A. That's the one down here.**
Q. The Table 1.
**A. Oh, Table 1, sorry. Environmental temperature. Here. Yeah, got it.**
Q. For the Bair Hugger forced-air warming, it was 24.4 degrees plus or minus 5.2 degrees; correct?
**A. Yes.**
Q. So that means sometimes the temperature in that area was all the way up to 29.6 degrees Celsius.
**A. Yeah. Probably not quite, but approximately, yeah.**
Q. Okay. And then it could have gone down to like 19.
**A. Yeah.**
Q. Okay. And -- and that would be --
Is that the standard deviation?
**A. Yes, it is.**
Q. Okay. And for the Hot Dog, it was only 22.6 degrees plus or minus 1.9 degrees Celsius; correct?
**A. Uh-huh, yes.**



Q. The standard deviation is much more lower for the Hot Dog than it is for the Bair Hugger; correct?
**A. Correct.**
Q. Okay. And the p-value here, which is the statistical significance, is .01; correct?
**A. Correct.**
Q. Which means this data is statistically significant; correct?
**A. Different, yes.**
Q. Okay. Which means, based on this data, the Bair Hugger warms the air around the surgeons and the patient more than the Hot Dog; correct?
**A. The air is warmer, yes.**
Q. Okay. And that warm air is coming from underneath and around the -- the -- the -- the warming devices; correct?
MR. GORDON: Object to the form of the question.
**A. I assume yes. Yeah.**
Q. Where else would the warm air come from?
**A. I don't know.**
Q. Okay. Most likely it's coming from the warming devices; correct?
**A. Correct.**

Q. And these were orthopedic patients; correct?
**A. Correct.**
Q. Do you know what types of surgery were being performed?
**A. I thought it was hips. Did we not say that?**
Q. It --
I could not find it, but if you recall correct -- if you recall --
**A. It's not good that we were not more specific. I -- I would have thought hips, but I'm -- I'm not sure.**
Q. And -- and just to --
Are you done? I'm sorry.
**A. I'm done.**
Q. Okay.
**A. I'm done.**
Q. On the last page it says -- it states, "Patients undergoing very long, open surgery with potential large fluid shifts are at highest risk for perioperative hypothermia. In our study, the mean duration of surgery was 90 minutes, and the typical surgery was limited to the extremities without open abdomen and without massive fluid shifts." Did I read that correctly?
**A. Yes.**



Q. Is it my understanding that patients that have some sort of abdominal or open surgery in the core are much more likely to become hypothermic because of fluid shifts as compared to patients that undergo surgery in the extremities?
**A. I think this is correct.**
Q. I mean is that what this is saying pretty much?
**A. Yes.**
Q. Okay. So for a person that has a knee arthroplasty, he's less likely to become hypothermic than a person over time -- if you use time as a constant, okay -- than someone that's having an abdominal surgery.
**A. I believe that's true.**
Q. Okay. Is there any studies to support that, or is that just your clinical judgment?
**A. That's my clinical judgment.**
Q. Okay. And that is because based on the fluid shifts that are occurring in an open abdominal surgery as compared to an arthroplasty of a knee or hip.
**A. I wouldn't call it fluid shift. That's maybe not perfectly phrased. It's -- it's -- it's simply because of tissue exposed. So if you open an entire belly, you have a lot open, while if you have a small incision --**



Q. Okay.
**A. -- there's less -- less heat loss from the area. That's what it says there.**
Q. So the incision size has an effect on the temperature curve of a patient with respect to his core temperature.
**A. It might, but that's never formally been studied.**
Q. Okay. The only thing that's really been studied is colorectal.
**A. Right. And it was open at this point in time.**
Q. And under the "STUDY FUNDING" finally, this was funded by Bern University Hospital?
**A. Yes.**
Q. Okay. And you -- you were donated thermocouples by Mallenckrodt Anesthesiology Products?
**A. Yes.**
Q. And Hot --
And Augustine Biomedical Products donated the -- the Hot Dog device; correct?
**A. I believe so.**



Q. Didn't offer any funding or anything of such a nature based on --
**A. No. Otherwise, it would be --**
Q. Okay. And do you know whether or not Augustine had any editorial say in -- in this manuscript?
**A. I -- I doubt it, but I cannot remember.**
Q. Okay. Is Mercury Biomed the first company that you've been on the advisory board that's not forced-air warming?
**A. I think so, yes.**
Q. Going back to Exhibit No. 244, do you know whether or not the operating rooms in Switzerland, in Bern in the hospital were laminar flow?
**A. I believe the orthopedic ones were.**
Q. Okay. So this study was done in a laminar flow operating room.
**A. I believe so.**
Q. And were you there during the time --
Do you recall being there during the surgeries?
**A. No.**
Q. Okay.
**A. I wasn't there for all surgeries, no.**
Q. So were you -- were you aware of how the

patients were draped during -- during the study?
**A. In general, yes, but I didn't supervise everything among --**
Q. And what was your understanding of the draping procedure used in the -- the Brandt study of 2010, Exhibit No. 244?
**A. You know what? I'm not absolutely sure. I could only describe to you now how you usually drape a hip, but whether that was absolutely done this way, I don't know.**
Q. Do -- do the doctors in Switzerland drape hips similarly to doctors in the United States?
**A. I would assume so.**
Q. Well you've practiced in Switzerland; --
**A. Yes.**
Q. -- correct?
During the time of your prac -- during your practice as an anesthesiologist, did you attend or provide anesthesia services for orthopedic patients?
**A. Yes, but very little.**
Q. Okay. Going through this Exhibit 244, this article, does it refresh your recollection where the temperature sensors were to measure the environmental temperature?
**A. Huh-uh. The way it's --**



**No. The way it's written, I really can't tell because it says once it's in the anesthesia surgery area, so I -- I really don't know.**
Q. Is it possible that the one meter is just one meter up from the ground?
MR. GORDON: Object to the form of the question, lack of foundation.
**A. It's possi --**
MS. DIFRANCO: Go ahead.
**A. Oh. No, that is not possible. I think we would have always done it in -- at patient height, wherever the patient is.**
Q. Okay. Are you familiar with the Scott study that looked at -- out of Johns Hopkins that looked at the SCIP-10 protocol?
**A. Yes, I am.**
Q. Do you know Andrew Scott?
**A. Hmm?**
Q. Do you know Andrew Scott?
**A. Huh-uh. Huh-uh. I don't.**
MS. DIFRANCO: Is that a no?
THE WITNESS: No. Sorry.
Q. Do you know any of the authors of this study from Johns Hopkins?
**A. Frank.**



Q. Steven Frank?
**A. Yes.**
Q. How do you know Steven Frank?
**A. I have known him for the past 20 years.**
Q. Is he a reputable doctor?
**A. Absolutely.**
Q. And he's done research in the field, especially in -- in myocardial infarction?
**A. Yes.**
Q. All right. Were you part of the meetings with the government or Medicare with respect to the SCIP protocols?
**A. No, I was not.**
Q. Do you know why they discontinued SCIP-10?
**A. No, I don't.**
Q. Do you know what SCIP-10 is?
**A. I do.**
Q. What is SCIP-10?
**A. The --**
**As far as I understood, it was one of our performance measures in regards to temp -- core temperature of patients at the end of surgeries or at arrival. So patients either had to have a core temperature at the end of surgery of greater than 36, or there had to be proof of active warming.**



Q. Okay. So if you -- if you active warm and the patient is below 36 degrees, --
**A. That's fine.**
Q. -- you could file a SCIP-10.
**A. Exactly.**
Q. Or if it's a surgery that is short or whatever, you don't -- and the patient comes out at 36 degrees or above, you still comply with 610 -- or SCIP-10; --
**A. Yes.**
Q. -- correct? Okay.
(Exhibit 245 was marked for identification.)
BY MR. ASSAAD:
Q. Dr. Kurz, what's been marked as Exhibit 245 is an article titled "Compliance with Surgical Care Improvement Project for Body Temperature Management (SCIP Inf-10) Is Associated with Improved Clinical Conditions." Are you familiar with this document?
MR. GORDON: It's "Outcomes," not "Conditions."
MR. ASSAAD: "Outcomes," correct.
**A. Yes, I am.**
Q. Okay. Have you looked at the data in this document?

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**A. Yes, I did.**
Q. Okay. Have you had any conversations with any of the authors regarding this document?
**A. No, I have not.**
Q. Any conversations with Dr. Sessler regarding this document?
**A. Probably, yes.**
Q. Okay. If -- if you look at -- just --
Just to get a background of this -- of this study, this was a retrospective study done at Johns Hopkins; correct?
**A. Correct.**
Q. And it was regarding --
And they looked at 46,683 patients that underwent non-cardiac surgery between January 2010 and June 2014; is that correct?
**A. That is --**
**If I find it here, it's correct.**
Q. On the second page.
**A. Oh, you're back there. Okay.**
Q. Under "Materials and Methods."
**A. Okay. Yeah.**
Q. Okay. And on the following column where it starts with "Two groups...," it says, "Two groups were created based on the SCIP-10 guideline, which was

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designed to be the 'SCIP compliant' and 'SCIP noncompliant' groups. If the highest of the two temperatures measured during the last 30 minutes of surgery and the first 15 minutes of postoperative care was greater than or equal to 36 degrees, or active patient warming was utilized..."
**A. Correct.**
Q. And that's what we discussed previously; correct?
**A. Yes.**
Q. Okay. Now if you look on Table 2, they looked and not just colorectal surgery but over many different types of surgeries; correct?
**A. Correct.**
Q. General surgery, gynecology, neurosurgery, spine, orthopedics, otolaryngology, plastics, pediatric surgery, thoracic, transplant, urology, and vascular; correct?
**A. Uh-huh. Correct.**
Q. Okay. So they looked at the effect of SCIP compliance or maintaining normothermia over many different types of surgeries.
**A. Correct.**
Q. Okay. And if you look at Table 4, and I want to focus on wound infections because that was

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mainly what the infections that were discovered during the 1996 Kurz study; correct?
**A. Yes.**
Q. Okay. You agree with me that there's no statistically significant difference between SCIP compliance and SCIP non-compliance.
**A. Yes.**
Q. Okay. So what this is study -- this retrospective study is telling me, that in general there's no statistical difference in wound infections between patients that are SCIP compliant, which is either active warming or -- or they maintain normothermia, and SCIP non-compliant; is that correct?
**A. I assume it is.**
Q. Okay. And you have no reason to disagree with these numbers; correct?
**A. Other than that they're very small, no.**
Q. For -- for wound infection, I mean this forty -- forty-three thousand patients.
**A. Right. But 44 SCIP non-compliant wound infections.**
Q. Yeah, 44 out of 44,000.
**A. Forty-four out of 1,200.**
Q. Where do you get 1,200?
**A. In the same --**

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Q. Oh, okay.
**A. So it's --**
**Anyway, --**
Q. Okay.
**A. -- I believe the data, but it -- it has problems.**
Q. Do you think it's underpowered?
**A. I don't want to talk about power here. I would have to really reread that article because I know I had some concerns about it. I just can't remember them now.**
Q. Okay. Now this is not saying that, if you look at the individual type of surgeries, that you're not going to see a statistically significant difference; correct?
**A. Correct.**
Q. You're looking at the overall trend.
**A. Correct.**
Q. Okay. And -- and if you turn to Table 3, what's -- what's interesting is the paper --
**A. I don't --**
Q. Table 3.
**A. Yeah. Yeah. This is -- yeah. This needs to be reread because why there should be a difference in sepsis is unclear, because sepsis is the worst form**

**of infections. So I would need to reread that.**
**Okay, Table 3.**
Q. Okay. I'm talking about --
But wound infections, you agree with me that there's no statistically significant difference based on this data.
**A. Yes.**
Q. Okay. Table 3 talks about SCIP compliant and SCIP non-compliant, and for SCIP non-compliant means that you're not above 36 degrees and you received no active warming; correct?
**A. And/or, yes.**
Q. Okay. So there's no active warming, and you do not leave the operating room at 36 degrees, according to the criteria, or within 15 minutes --
**A. Right.**
Q. Okay. And -- and for those patients, we're seeing an end operating room temperature -- core temperature of 35.1 degrees.
**A. Yeah.**
Q. Okay. So that that's higher than, you know, the uncooled patients in your study that were 34.5 degrees.
**A. That's right.**
Q. And we're seeing patients -- the difference



between the SCIP compliant and the non-SCIP compliant -- let's start with this -- withdraw.
The difference with the SCIP compliant and the SCIP non-compliant, we're looking about -- a change of temperature of about, what, 1.2 degrees on average.
**A. Yes.**
Q. Okay. You agree with me sitting here today that there's no evidence that a one-degree change of temperature in the core body temperature has any effect on infection rates.
**A. I agree that there's very little evidence for that, yes.**
Q. And if you look at page six of Exhibit No. 218 --
**A. Which is what?**
**Give me one second with this one here, please. How did they measure that?**
**Which one?**
Q. Exhibit 218, --
**A. Oh.**
Q. -- page six. Under the seventh line up it says AK, DK, CL. Do you see that?
**A. Seventh line up. Yeah.**
Q. Okay. And AK is you; correct?



**A. I assume, yeah.**
Q. DK is probably a typo because there's no DK listed here, and CL is Claude LaFlamme. Do you know Claude LaFlamme?
**A. I do.**
Q. Okay. And this is based from a question, if you go up, "why should 3M fund a study to show risk associated with hypothermia when there's already broad acceptance of the current evidence?" And one of your responses is, "...since you've already proven out the risks of 2 degrees of hypo. Worse case it would show 1 degree doesn't matter." Did I read that correctly?
**A. Yeah.**
Q. Okay. So sitting here today, you don't know if one degree of hypothermia has any effect on infection rates.
**A. Yes.**
Q. Correct?
**A. I think I've said that several times.**
Q. Okay. So if --
And that's one degree below 36 degrees; correct?
**A. I can't remember how we -- one -- one degree. It's --**
**No, I would say it's one degree below core**



**temperature.**
Q. Well what we --
I mean do you remember what you were talking about here? Were you talking about core temperature or --
**A. I can't remember.**
Q. Okay.
**A. I cannot, no.**
Q. Well if these studies are showing that the core temperature is less than one -- one degree with -- with non-compliant patients at 35.1 --
**A. Uh-huh?**
Q. Okay.
-- and there's no evidence to support active warming at that point, what evidence is there to support active warming and maintaining normothermia in 2016?
**A. I think there is a little ev -- evidence that we have from 20 years ago.**
Q. Little evidence -- excuse me?
**A. That the --**
**It's in fact still there, old wound-infection study we did, which might not be to today's standards but very much was to standards at that point in time. This study doesn't prove that the opposite**

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**is true either, because don't forget, it's a retrospective study and not one of the best-done either. So you --**

Q. Based on in today's standards.

**A. Based on in today's standards.**

Q. Okay. It might have been good standards back in 1996.

**A. There's no discussion about it because the data would not have been available in '96.**

Q. Okay.

**A. So we still only have the old data.**

Q. Okay. And Dr. Sessler has mentioned in an e-mail before, in today's standards and with respect to reliability of studies, that he probably wouldn't have published the 1996 Kurz paper. Do you agree with him?

**A. Absolutely.**

Q. Okay.

**A. I would not have either.**

Q. So without that paper meeting today's standards, do you agree with me that there's no scientific evidence today that active warming or maintaining normothermia reduces the incidence of infection?

**A. If -- I mean if -- if you exclude the only**

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**paper that shows that, then there is no evidence.**

Q. Well we discussed later there's only one paper regarding infection rates; correct?

**A. You could --**

**You have a second one which you excluded: the Melling paper.**

Q. Well you couldn't tell me whether or not that was intraoperative warming; correct?

MR. GORDON: Objection.

**A. It doesn't matter.**

Q. Okay.

**A. It does not matter. We are talking about maintenance of normothermia, --**

Q. Okay.

**A. -- whether you warm the patients --**

Q. Do you think Melling was a good study?

**A. It was an okay study for the time.**

Q. Would you agree with me that that wouldn't be publishable today?

**A. I absolutely would agree with you.**

Q. Okay. So sitting here today, what paper that could -- that -- what evidence that could be published today supports active warming in the -- in the active warming and normothermia that reduces the incidence of infection?

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**A. Very little.**

Q. None; correct?

**A. I'm not quite sure. I'm -- I'm still -- I'm still debating about blood loss and other studies.**

Q. Talking about infection.

**A. Yeah.**

Q. So I just want to get this clear for the record. You agree with me that, in today's scientific community, that there's no evidence, publishable evidence that supports that maintaining normothermia reduces infection rates. You agree with that statement.

**A. Still have problems with that statement.**

Q. Do you want me to rephrase?

**A. Yeah. Do that, please.**

Q. In today's scientific standards, there is no reliable evidence that supports that maintaining normothermia reduces the incidence of infection.

**A. That is correct.**

Q. Thank you.

MR. ASSAAD: Take a break. I need to use the restroom.

THE REPORTER: Off the record, please.

(Recess taken.)

BY MR. ASSAAD:

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Q. Going -- going back to my last question: In fact, as early as 2012 you notified 3M that the current research guidelines for reliability and that the previous studies were not done -- were done with much -- I'm sorry. Rephrase.

Back in 2012 you notified 3M that, at the KOL meeting in Washington, that the evidence for hypothermia-related complications mostly does not meet current research guidelines for reliability and that previous studies were done with much larger temperature differences than are currently allowed. Do you recall saying that to 3M?

**A. That is correct.**

Q. Okay. And are you aware since that time 3M has continued to cite your paper for its marketing purposes with respect to its claim that forced-air warming is a way to maintain normothermia, which reduces the incidence of infection?

**A. I agree with this.**

Q. You agree that you're aware that mar -- that they continue their marketing.

**A. Yes. And I agree that they do that. I do the same.**

Q. Okay. And you've been requesting from them since 2012, you and Dr. Sessler, to fund studies to --

larger studies to support those claims that were made or those observations or -- or results that were found in the Kurz study; correct?

**A. That's partially correct. We asked to do a study, first of all, larger patient populations but more importantly smaller temperature differences. And the smaller temperature differences we only have nowadays because all patients are warmed; otherwise, we would still think my '96 paper is very relevant.**

Q. But you're still looking at just colorectal; correct?

**A. No, we are not.**

Q. Well on the -- on the Protect study it's colorectal.

**A. Protect study says any type of --**

Q. Okay.

**A. -- other than -- any type of non-cardiac surgical patient population.**

Q. And when is that study supposed to be completed?

**A. I would --**

**Well, you should never ask things like that. It's three years.**

Q. Three years from --

**A. Three years from now.**



Q. Okay.

**A. From the beginning, yeah. But it should be beginning soon, should be beginning soon.**

Q. Do you agree that not all patients need to be actively warmed?

**A. Yes, I do agree.**

Q. Do you have any scientific evidence that patients -- withdraw that.

What's your definition of "passive warming?"

**A. Basically, any type of covering with blankets or draping, anything that does not actively transfer heat into the body. To a certain extent, even a warm blanket isn't very much -- it's almost passive heating.**

Q. So a warm blanket is considered passive?

**A. No, I think in the literature it's considered active, but it transfers so few calories -- watts that it's not much of an active device or a venue to warm.**

Q. Do you agree that in some surgeries, passive warming could be as effective as active warming?

**A. I agree that in some surgeries active warming is not needed and therefore passive warming is sufficient.**

Q. What surgeries would they be? Can you give



me some examples?

**A. Yeah. Your eye.**

Q. Okay. What about surgeries lasting less than an hour?

**A. I --**

**With current knowledge, I probably would agree that active warming might not be needed.**

**(Exhibit 246 was marked for identification.)**

BY MR. ASSAAD:

Q. Dr. Kurz, what has been marked as Exhibit 246 is an e-mail from Al Van Duren to you and Dr. Sessler, at the bottom part of the e-mail, regarding two drafts of temperature papers that were coming up for publication in 2013. Do you recall receiving this e-mail?

**A. I don't.**

Q. Do you know what two papers he's referring to?

**A. I don't. I assume one is the descriptive temperature study, the --**

Q. Targeting Normothermia?

**A. No, not Targeting Normothermia. The one we discussed before that included transfusions.**

Q. Okay.



**A. I assume that --**

Q. They -- they funded that study; correct?

**A. I think they did.**

Q. Yeah. Okay. And what was the other one?

**A. I don't know because there's no other one be -- we -- we -- we've published.**

Q. So at the bottom of the e-mail -- or the top of the e-mail it says, "Hi, Dan and Andrea," and I assume that's Dan Sessler and Andrea Kurz; correct?

**A. Right.**

Q. At the bottom says, "Gary Hansen and I have read the two drafts of the temperature papers, and I was wondering if we could make some suggestions concerning amplification and explanation of some of the concepts. I promise that they won't be too commercial." Do you see where I read that?

**A. Yeah.**

Q. Okay. Was there -- was there an issue with 3M, anyone from 3M, to try to make edits in publications they funded, that they want to put some commercial -- like stuff that would make the edits too commercial in the past?

**A. No.**

Q. Do you know --

Do you have any reason why Al Van Duren

would put that disclaimer in an e-mail to you?
**A. I cannot even remember which two papers those were.**
Q. Dr. Sessler responded --
**A. I don't know.**
Q. -- to Al Van Duren, "Dear Al,
"We are in the process of submitting the papers. Thus, every comment would have to be incorporated really quickly. I assume, if we get your suggestions by next week we can still incorporate them." Did I read it correctly?
**A. Yes, you did.**
MR. GORDON: Read the signature. I think you misspoke.
Q. Oh, I'm sorry. It was from you. Sorry. This is an e-mail from you to Al Van Duren; correct?
**A. Yeah. I don't know which the second paper was. I'm sorry.**
Q. Well whatever paper it was, you were willing to hear suggestions from Al Van Duren and incorporate them into a paper.
**A. Obviously, yes. Yeah.**
Q. Okay. Do you know whether both papers were funded by 3M?
**A. If I don't know which the second one was, I**



**don't know, no.**
Q. Well I guess my question --
You have a contract. Isn't it by contract, before you submit it for publication, they have a right to -- to look at it and make suggestions?
**A. Absolutely.**
Q. So why in this process you were about to publish it before you get the final okay from 3M?
MR. GORDON: Object to the form of the question.
**A. I don't recall why that happened.**
Q. I mean you write, "We are already in the process of submitting the papers."
**A. Yeah.**
Q. So it means you're in the process of submitting the papers for publication; correct?
**A. Yeah.**
Q. Do you agree at this point in time that you haven't received any suggestions from 3M regarding to any comments or edits they want to make?
MR. GORDON: Object to the form of the question, and also lack of foundation.
**A. Yeah.**
Q. Have you ever had any con -- conversations with Michelle Hulse Stevens about the 1996 study and



that -- that it won't -- it won't hold under scrutiny in the future?
**A. I might have. I don't know.**
Q. Do you recall any conversations with Michelle Hulse Stevens about informing her that the 1996 study is not reliable and we need -- or it's not -- doesn't meet today's reliability standards and that we should get funding for a new study?
**A. Might very well be.**
Q. Do you recall having a pitch or proposal to -- to Michelle Hulse Stevens?
**A. I'm sure we had over the last few years.**
Q. But you don't recall anything --
**A. I don't recall when or why and --**
Q. You -- you agree that there's part of the scientific community that believes that there's not enough scientific evidence to support maintaining normothermia during the intraoperative period.
MR. GORDON: Object to the form of the question.
**A. I actually don't believe that.**
Q. You've never read any articles by doctors in South Carolina that talk about normothermia being -- being as a false idol?
**A. No. Who -- who was that?**



MS. DIFRANCO: Answer his questions.
THE WITNESS: Yeah. No.
MS. DIFRANCO: You can't ask him questions.
Q. Medicine today is -- we --
We practice evidence-based medicine today; correct?
**A. We try to.**
Q. Okay. And the research --
And it's based on research that's evidence-based; correct?
**A. Again, we try to.**
Q. Okay. In 20 years since the Kurz study, 3M has been using that study to extrapolate that the incidence of infection is reduced when you maintain normothermia, not across just colorectal surgeries but across all surgeries. Are you aware of that?
**A. Yes, I am.**
Q. And at any time have you contacted 3M and told them, "Look, colorectal, you know, is -- is an open abdominal surgery, there's not enough evidence to support -- to maintain those statements in any other type of surgery?"
**A. I'm always very specific in regards to patient-population studies, so I might, but I don't recall it.**

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Q. So you think you may have told 3M that you can't make those claims?
**A. I may have had a conversation, but I really -- in 20 years, I -- I don't remember that.**
Q. Would it have been with Dr. Augustine?
**A. I had very few conversations with Dr. Augustine.**
Q. Has Dr. Augustine ever asked you to be on his advisory board for Hot Dog?
**A. He might have many years ago.**
MR. ASSAAD: I think that's all I have.
MR. GORDON: Yeah. And given the doctor's need to finish in a half --
THE WITNESS: No, it's fine.
MS. DIFRANCO: Let's keep going for -- Let's go off the record.
THE REPORTER: Off the record, please.
(Discussion off the stenographic record.)
BY MR. GORDON:
Q. Dr. Kurz, I'm Corey Gordon. I represent 3M. I want to start with asking you some follow-up questions on Exhibit 245. That's the Scott paper.
**A. Uh-huh.**
Q. SCIP Inf-10.

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**A. SCIP-10. Yeah. Where did I put that?**
Q. It's right there. I -- I'm -- I want to clarify because I'm not sure I heard you correctly. Are you --
Is it your testimony that there is no evidence today to support the notion that maintenance of normothermia reduces infections, any kind of infections?
MR. ASSAAD: Objection, misstates prior testimony.
MR. GORDON: And it may well. I'm -- I'm just --
So please clarify.
**A. I think I can't -- it's difficult. I don't know why you -- why we talk about it in regards to this. I mean there are published papers that show that under certain conditions there is an effect of maintaining normothermia.**
Q. A -- a beneficial effect?
**A. It causes a beneficial effect.**
Q. Let's -- let me be specific on -- because it was in the context of the Scott paper that -- that -- that this arose. If you look at the -- the -- just the re -- the front page, the results, they -- they say sort of in the middle, "...SCIP compliance was

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associated with a reduced incidence of hospital-acquired infections...," then they go on to give the numbers and the odds ratio.
Would you consider the Scott paper evidence that maintenance of normothermia has a beneficial impact by -- in -- in -- in terms of reducing the incidence of hospital-acquired infection?
MR. ASSAAD: Objection to form.
**A. I do. I -- I do. And that's what I actually wanted to get to. I mean only that this is a retrospective study. Wound infections are very, very poorly coded; however, they did have things like sepsis and other really, really important infectious outcomes that were reduced. So in the end, I don't care which type of infection it is, --**
Q. And --
**A. -- that it's clear there is a positive effect or a decreased infection incidence in patients that were SCIP compliant.**
Q. And by "SCIP compliant," that -- that means maintenance of normothermia.
**A. Either --**
MR. ASSAAD: Objection.
**A. -- greater than 36 and/or warmed intraoperatively.**

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Q. Okay. And on page five they -- under "Discussion" they go -- they say that "The primary findings in this study were that SCIP Inf-10 compliance was associated with a reduced risk for hospital -- hospital-acquired infections, ischemic cardiovascular events, and mortality, as well as a decreased length of stay."
Based on --
**A. That's the first paragraph of the "Discussion," is it? Yes.**
Q. The first -- first line of the discussion.
**A. Yeah, yeah. Uh-huh.**
Q. And I'm --
Do you disagree with any of those --
**A. No, I don't.**
Q. -- conclusions?
And based on the state of evidence today in January of 2017, do you think there's any --
Do you think this is an outlier, or do you think this is consistent with the existing body of -- of -- of medical literature, --
MR. ASSAAD: Objection to form.
Q. -- including all your work?
**A. That's the most recent body. There it's -- it's -- it's clearly consistent what we did many years**

**ago, it's under different conditions, but that's the body of literature we have at the moment.**

Q. And in a little bit further on they go on to say, "Our findings also support those of the original randomized clinical trials by Kurz et al and Frank et al, on which the SCIP measure was based..."

**A. Right.**

Q. So by --

Okay. Right. And I -- so are -- are --

Do you consider the Scott study or the Scott paper to somehow call into question your original paper, the 1996 paper?

MR. ASSAAD: Objection to form.

**A. I don't, despite the fact that the -- the strict wound infections don't seem to be different, but I'm not taking it so seriously because those are usually very hard to evaluate. So I absolutely agree with that paper.**

Q. And on -- with respect to that, I think they -- they -- they -- I -- I'd like to direct your attention to page six --

**A. Just one further, yeah.**

Q. On the -- the bottom of the first full paragraph they say, "We also had a lower risk population for wound infection compared with the



randomized trial by Kurz et al, where all patients had colorectal surgery. This may explain why in our study the composite infection outcome was significantly increased but wound infection by itself was not."

**A. Yeah. And I think this was what we said before. There were very few wound infections, real wound infections in this particular study.**

Q. And in this particular study there were only a total of 46 orthopedic procedures that were SCIP non-compliant; right?

**A. Yeah.**

Q. And the overall rate of infection in orthopedics tends -- tends to be one percent or less; right?

**A. I would say less than one percent.**

Q. Even if you say it's one --

MR. ASSAAD: Objection to form.

Q. Even if you assume it's one percent, with a population of 46 procedures, you -- you wouldn't expect --

**A. I would be --**

Q. -- even to get one infection.

**A. Exactly, yeah.**

Q. So in terms of the -- the -- the pow -- the ability of this study to demonstrate the absence or



presence of any benefit from the maintenance of normotherm -- normothermia on wound infections, specifically in the context of orthopedic procedures, do you -- do you believe this study has any -- has any value?

MR. ASSAAD: Objection to form, assumes facts not in evidence.

Q. That's -- that's a -- that's a poor question, --

**A. Yeah.**

Q. -- poorly-phrased question.

MR. ASSAAD: I interrupted. I'm sorry.

Q. Would -- would -- would you consider this study evidence that maintenance of normothermia confers no benefit in orthopedic surgery --

MR. ASSAAD: Objection --

Q. -- in terms of reducing the risk of infection?

MR. ASSAAD: Objection to form, assumes facts not in evidence.

**A. Let -- let me rephrase that.**

Q. Please.

**A. I con --**

**I think in regards to orthopedic surgery and wound infections, these patients, this study cannot**



**make a statement -- not make any statements.**

Q. Okay. And have -- have you -- are --

Have you done any research to try and find if there are any, you know, studies or papers out there now that address the impact of normothermia on surgical-site infections in orthopedics?

**A. No.**

Q. Okay.

**A. No, we don't.**

Q. All right. You had --

In your earlier testimony you had said you had some concerns about the Scott paper but you -- you couldn't remember what they were.

**A. Uh-huh. I do now.**

Q. You do now?

**A. Yeah.**

Q. Please share them.

**A. The main concern actually was again there's a -- the --**

**The SCIP non-compliant group is very, very small, and I -- I -- I remember now because I -- I think at some point I actually reviewed the paper, so you go 44,000 patients where there's 12,000, and then the -- I -- I actually like it that they make no statement or basically explain the wound-infection**

**data just because they had such low numbers of those, which is very, very typical for retrospective studies. It's like not in our colorectal patients we exactly evaluate that every day. These are just electronic data where it's not done.**

**The other objection -- not objection, but the other thing I -- I didn't agree so much was their temperature data, whether SCIP compliant or non-compliant, because it's not completely clear how they measured that, whether it was esophageal -- I think most of it was actually some type of infrared or so measurement which isn't very reliable.**

**So those were my main concerns, which in the end don't make -- don't matter that much because temperature is -- is -- is a side effect here. They -- they looked at SCIP compliant or non. So -- yeah, so they should have fairly accurate temperature measurements.**

Q. Okay. So your -- your 1996 study, --

**A. Yes.**

Q. -- your -- you said it wouldn't -- you wouldn't consider it publishable today. What are the reasons for that?

**A. I'm -- I --**

**Did I really say that I wouldn't consider it**



**publishable?**

Q. I -- I --

**A. I don't think I said it in those words.**

Q. I --

Don't let me to put -- well don't let me put words in your mouth.

**A. I think it might not be publishable as well as we did it 25 -- 20 years ago. So that 1996 study was the first anesthesia outcome study in patients ever, and I think that's why it was published so well. It probably is --**

**What we see more in -- more now in medical research is that numbers truly matter, so you do get some degree of false or by-chance results if you don't study very, very large numbers. At the point in time this was the largest anesthesia study ever. Nowadays we consider studies that are 5,000, 10,000, 20,000 patients the appropriate size. So you can see, though I -- I think I could still pub -- you could still publish it nowaday, but I -- I -- I -- I guess the approach to -- to patient populations and how large studies are have significantly changed over the past 20 years.**

Q. So if you were to redo the study, the 1996 study today, you would increase the patient



population; --

**A. Yes.**

Q. -- is that right?

**A. Yeah.**

**I couldn't redo the study, the exact study, no.**

Q. Please explain to the jury why you couldn't redo the study today.

**A. Because it would be considered unethical nowadays not to warm a patient at all intraoperatively. No eth --**

Q. Fine.

**A. No ethics committee -- it's become --**

**Over the past 20 years, active warming has become standard of care, and with no study you can deviate from the standard of care. So 20 years ago, having a control group that wasn't actively warmed was perfectly fine because nobody else in the world warmed patients. Nowadays it wouldn't.**

**The other thing is, of course -- and that's one reason why we are looking at much larger patient populations. Due to the fact the patients are warmed, we don't see the significant decrease of hypothermia any more, and therefore in any study the effect size wouldn't be as large as in this particular one.**



Q. I under --

Putting aside the ethical -- your -- your constraint that would prevent you from doing a study without an act -- without active warming, --

**A. Uh-huh.**

Q. -- if you were to replicate the study today with a larger patient population, do you believe that it would show no impact of warming on infection rates?

MR. ASSAAD: Objection, calls for speculation.

**A. I think if I would replicate this study I would see a significant effect, an improvement in infection rate, maybe not the same effect size.**

Q. And earlier I think there were some questions about some comments that had been about made either by you or -- or Dr. Sessler that maybe the effect size would be only 30 percent. Do you recall those?

**A. Yes, I do recall that.**

Q. And -- and I -- I understand that's just your -- your -- your best judgment --

**A. Yes.**

Q. -- based on your expertise and -- and experience. But what -- I --

I want to make it clear. You're not

saying -- or are you saying that you -- you -- that the evidence today no longer supports the idea that act -- that maintenance of normothermia reduces the risk of surgical-site infections?

MR. ASSAAD: Objection to form.

**A. I think, if I understand you correctly, I'm not saying that. I am saying that I still believe that maintenance of normothermia decreases infection risk, but the effect size might be closer to 30-percent reduction or so, which in effect is a humongous, enormously large effect size for any medical intervention.**

Q. And you were asked about some -- apparently some doctors in South Carolina who -- who seem to think that maintenance of normothermia is -- is completely unimportant. Would you -- is that something with which you --

Are you familiar with any sizeable or, you know, appreciable number of physicians or school of thought that actually is -- questions the -- the value of normothermia today?

**A. No, I'm not. That's why I was so surprised. No, I'm not.**

Q. In fact, have you ever heard of any doctors who question normothermia as -- as a -- as a positive



benefit?

**A. Not in the past 10 years or 15 years.**

Q. Okay. You had -- and --

And you earlier talked about more-recent studies that you -- that meet the more-modern standards of evidence -- evidence-based medi -- medicine to support the positive impact of normothermia on several other outcomes.

**A. Yes.**

Q. Okay. We talked -- you --

You talked about blood transfusions. And if it reduces the need for blood transfusion, does -- does that have any potential to impact the -- the host immunity?

**A. Enormously, yes.**

Q. Yeah. How so?

**A. Because blood transfusions in itself are to a certain -- are very immunosuppressive, so if --**

**There's a very large body of evidence that patients who receive blood transfusions have more post-operative infections, more sepsis, more cardiac and pulmonary complications, so avoiding blood transfusions is actually one of our main -- main goals -- not avoiding, but limiting the number of transfusions is one of the main goals here at the**



**Cleveland Clinic and many other places nowadays.**

Q. So in terms of that, you know, evidence supporting the notion that normothermia confers a benefit in terms of reducing the risk of infection, perhaps the evidence for the reduced transfusions is not direct A-to -- A-to-B evidence but it's A-to-B-to-C.

**A. It's a mediator.**

MR. ASSAAD: Objection to form.

Q. I'm sorry. You -- you said it was --

**A. It's almost like a mediator. So if you are -- it -- or it's -- it's a --**

**It's part of a mechanism, let's put it that way. So if you are hypothermic, you lose more blood. And that's actually pretty well established, because hypothermia directly affects platelet function. If you -- if you -- if you give transfusions, then you get some immunosuppressive effect and -- which decreases the host response which then could -- but I'm extrapolating now, so --**

**But that's the clinical pathway which I think that follows.**

Q. And the study that you're -- you and Dr. Sessler are doing now in China, what -- what's the primary outcome that you're -- you're looking at



there?

**A. I think the primary outcome is myocardial injury after non-cardiac surgery, but I do believe -- we've gone over the protocol so often that I'm getting confused -- that the secondary outcome is wound infection.**

Q. But in terms of primary infection, the myocardial injury, is that -- is -- is -- is the -- the injury that you're looking -- you're going to be looking for, is that something that -- that the -- the average patient would realize they've been injured?

MR. ASSAAD: Object to the form.

**A. Yes, it is, because they either would have a myocardial infarction after surgery, which they would know very well, or they would have some type of injury which is not quite as bad but still a bad complication after surgery. And myocardial injury after surgery happens in almost 10 percent of our patients, so it's a huge -- a huge, huge medical problem.**

Q. And -- and I'm -- I'm --

I apologize for completely misunderstanding the purpose of the study. Is -- I --

Is there some chemical that is evidence of a -- a relatively mild cardiac damage --

**A. Yeah.**

Q. -- that -- that you can look for that somebody might be walking around and having no idea that they've had this mild mardi -- myocardial damage, but it has -- but it manifests itself in a measurable way with this particular chemical?

**A. We look at what's called troponin T, so that's a cardiac enzyme that's ex -- well it's excreted by muscle cells when they die, and it's a very, very sensitive marker, and they're a very strong predictor of post-operative mortality.**

Q. Are -- and is --

Are you going to be looking at troponin T?

**A. Yes.**

Q. Is that -- is that the primary outcome?

**A. Yes.**

Q. Is it --

So is the level of troponin T that you're -- you're looking for such that it would demonstrate that somebody's already had enough cardiac injury that they -- they ought to know about it?

**A. It would, yes. So the higher the level, the more likely that the patient has strong symptoms. The problem with -- with surgery or the post-surgery period is just that patients don't get the typical myocardial-injury chest pain, and so most of -- of --**



**of the myocardial injury is silent. Nevertheless, about I think one in 10 patients who have an elevated troponin level after surgery will be dead 30 days after surgery, which is -- it is significant.**

Q. And -- and -- and I'm -- I'm clearly not asking very clear questions and I apologize. But are -- is -- are any of the -- strike that.

At the levels of troponin that you're going to be looking at as the primary outcome, do you -- will you include as an adverse outcome from surgery troponin levels that are actually subclinical, that -- that have not manifested themselves --

MR. ASSAAD: Object to form.

Q. -- in overt cardiac disease?

MR. ASSAAD: Object to form.

**A. There is not such a thing. So anything that is considered relevant, which are troponin levels greater than .03, we will include; anything that's lower than that is too minimal that we won't. So it's --**

**The differentiation between clinic and subclinic is very hard to make here.**

Q. Okay. And there -- there was a study that had similarly looked at myocardial -- or the impact of normothermia on myocardial events, a Frank study.



**A. Yes.**

Q. Okay. And that --

Are you in effect trying to replicate that aspect of the Frank study with a -- a larger population and -- and --

**A. Yeah.**

Q. -- more --

**A. The Frank study did not measure troponin, which is a strong weakness of the study. But of course, then, 20 years ago, troponin wasn't as available and as established as they are nowadays.**

Q. Twenty years from now maybe there will be something else to --

**A. I hope so.**

Q. A more sensitive measure.

**A. Yeah.**

Q. Okay. If I could now direct your attention to Exhibit 244, the -- the Brandt et al paper on comparing the resistive polymer to forced-air warming, want -- and if you want to turn to page 37, I want to read you part of the discussion that we -- plaintiffs' counsel asked you about. He didn't read this, so I'm -- my turn to -- to read it, a portion of it.

MR. ASSAAD: Object to the preamble.

Q. "First, the blanket is stiffer and tends to



wrinkle, which may reduce the surface area in contact with the patient's skin, thus reducing its effectiveness. Because there is no stream of warm air, the efficacy of the system, similar to all resistive-warming systems, is dependent on close skin contact, and the blanket has to be placed on the patient correctly. Incorrect placement may explain the observed tendency of the rewarming curve in the FA group to be steeper and the final mean core temperature in the RP group to be lower. Therefore, the results of our study should be extrapolated with care to settings in which the risk of severe intraoperative hypothermia is high, or those in which hypothermic patients must be warmed quickly from very low core room temperatures. Another limitation is that the RP blanket has to be cleaned between cases, thus requiring manpower and cleaning equipment to avoid contamination with pathogens."

First of all, did I read that portion correctly?

**A. Yes.**

Q. Okay. And I'm -- I'm going to actually start with the -- the -- the -- the last part of it first and work backwards. In -- in this section you're talking about limitations of the -- the

resistive-polymer blanket. In this case it was the Hot Dog; right?

**A. Yes.**

Q. And one of the things you're -- you're -- you're cautioning about is that they -- they have to be cleaned in between each surgical procedure, which takes manpower and cleaning equipment. And -- and -- and that has to be done; otherwise, there can be a risk of cross-contamination of pathogens from the one patient being directly placed on another -- on -- on another patient; right?

**A. Yeah, absolutely.**

Q. And going back up to the top where you talk about the tendency of the blanket to wrinkle, are -- are you aware of any impact that that tendency of it to wrinkle has had on the -- on how effectively it can be cleaned in between surgical procedures?

**A. I --**

**No, --**

MR. ASSAAD: Objection.

**A. -- I cannot -- I cannot comment on that.**

Q. Have you -- have you heard any concerns about challenges to -- to cleaning the blankets in between procedures?

**A. I haven't, but then I -- I know very -- I**



**only --**

**I don't know many institutions that use these types of warming.**

Q. And --

But a concern if you use one is that you -- you got to be sure to clean it thoroughly, including all the wrinkles, all the folds, because if -- otherwise, you could be directly transferring pathogens from one patient to another; right?

MR. ASSAAD: Objection to form.

**A. Yeah.**

Q. Now you had -- I -- I --

I believe you had said that when you wrote this, the cost -- you -- your understanding was the cost of the -- the Bair Hugger blanket was higher and the cost of the cleaning process for the resistive blanket or the Hot Dog was -- was lower? And --

**A. That I don't know. I -- I know that the -- that the forced-air blankets have come down significantly in price. I -- I've -- I've never really looked. I mean that's -- that's the discussion part of a paper where you can make assumptions, but I haven't looked into the cleaning part. But I do know that here at the Cleveland Clinic we more -- more -- for many of our devices, actually moved to disposables**



**because the cleaning process is very often tedious and equally expensive at least.**

Q. You -- and --

And way earlier in your testimony this morning I think you talked about the -- the switchover the -- from the use of the Bair Hugger to the -- the Stryker product, the Mistral unit --

**A. Yes.**

Q. -- at the Cleveland Clinic, and I -- I -- I --

You had said something about the comments of your -- of the -- the nurse anesthetists and -- in -- in using the Mistral blanket. What had --

What has been the feedback that you have received from your staff about the -- the use -- about the -- how the -- how the Mistral unit performs?

**A. I think people just had the feeling -- and that's, of course, anecdotal so you must be careful -- that fewer patients have a core temperature greater than 6 -- 36 degrees when they drop them in the recovery room as opposed to before.**

Q. Now are those data that you collect?

**A. These are data that we collect.**

Q. And is -- so have -- are --

Is there any discussion about doing some



sort of a -- a --

**A. I've already initiated this. It's a --**

**We already are performing a data pull to look into this.**

Q. So --

And what will you be looking at in that data set?

**A. We will look at --**

**I think we started using Mistral-Air two years ago, in November or so, so what we will do is we will choose two similar time periods, let's say February to -- February, March, April -- May, three months two years ago or one and a half years or -- or one and a half years ago or whatever it -- even this year, and compare core temperatures to a three-month period at the same time in a year -- in that year, the same months, but only three years ago or four years ago when we had the Bair Hugger.**

Q. So you would be comparing core temperatures at the com -- at time of completion of the surgery on arrival at PACU?

**A. No. We -- we have all --**

**We have core temperatures from after induction to anes -- of anesthesia to end of surgery and at arrival in the PACU.**

Q. So you can do the whole curve.
**A. So we will do the entire time-weighted average below a certain core temperature.**
Q. Is that something you're doing just for internal purposes, or do you -- would you expect to publish the results?
**A. I probably would not publish. It's a quality-improvement project, and I mainly do that to see whether I -- we want to stick to the Mistral-Air or go back to Bair Hugger.**
Q. Do you have any plans, as part of the -- this comparison of the Mistral to the -- to the Bair Hugger, to look at any other endpoints besides core temperature?
**A. No. No. Because it's -- it's probably -- Three months isn't a long-enough time period to have enough patients to look at other outcomes. It's not a bad idea, but we probably will -- And I think it's also different times. So if you look at data, whatever, in two thou -- 2012 and 2016, many things have changed in between. It will be a very unfair comparison to look at outcomes such as infections or myocardial outcomes because surgical technique might have changed over time, other things in the OR might have changed, anesthesia management**



**might have changed, so no, we will not look at outcomes.**
Q. So the driver of this --
**A. Is temperature.**
Q. -- particular quality-improvement project is the concern that -- the anecdotal concern that core temperatures are lower -- have been lower with the Mistral unit.
**A. Exactly.**
Q. Okay. I -- I'm sorry, I --
If we could go back to Exhibit 244, one other thing I want to ask you about: on page 837 you said, "...posterior patient-warming systems do -- do have the inherent disadvantage that warming the back of the patient in the supine position is suboptimal because of low perfusion in this area and the danger of pressure-heat injuries."
Could you explain what you meant by "pressure-heat injuries."
MR. ASSAAD: Where are you reading? Sorry.
MR. GORDON: Page 837 of -- this is Exhibit 244.
MR. ASSAAD: Yeah, but where I mean.
MR. GORDON: It's almost to the bottom of the second column.



**A. The bottom, "...the back of the patient..." Yeah. That just means that when you lie on the surface, the vessels on -- the perfusion on your back is a little bit compromised just all due to your own weight because you are basically lying on -- on your back, and if you apply heat to an area that has a slightly decreased perfusion, it could cause burns easier as opposed to if the perfusion would be completely okay.**
Q. So are -- are you familiar with the concept of, in connection with -- with resistive blankets, of thermal runaway? Does that have any meaning to you?
**A. That term does not.**
Q. Your face told me it doesn't.
**A. No.**
Q. Are you familiar with how the blanket regulates the amount of wattage that is sent to it?
**A. It depends on which kinds. Are we talking about water blankets or resistive heating?**
Q. Resistive, resistive blankets.
**A. I think I kind of know.**
Q. I think --
Are you familiar with the concept of a -- of a -- of a sensor on the -- the resistive blankets that -- that basically tells the unit how much power



to keep sending into the blanket?
**A. Yes.**
Q. Okay. And are -- are you familiar with -- with burns that have resulted from those sensors becoming covered up or un -- folded under?
**A. I have not used these devices since I was in Switzerland. We did a, years ago, a volunteer study in St. Louis which was a study where these devices -- where we had the first versions of these devices and we did get burns. Since then I think they have improved quite a bit so I've not really heard much about burn or even pressure necrosis with those.**
Q. Have you ever recommended to the Cleveland Clinic that it look into the possibility of switching over to resistive blankets?
**A. No.**
Q. Why?
**A. You know what? Not -- I always -- Honestly, no good reason. I think the newer -- there are very new blankets that even have pressure-relief systems in them, and those -- those might actually work fairly well. They're probably expensive. We've advised -- I've advised the clinic to switch to or to use water-based garments only because they're very**

**hard to use and they -- they not necessarily transfer enough heat. Otherwise, I don't know too much about resistive. This -- I think maybe this was, I think, the only study I really did with these devices.**

Q. Do you have any safety concerns about forced-air warming?

**A. No.**

Q. Way earlier, according to my notes, we did -- you were -- you were asked some questions about things in the operating room that blow air directly onto patients.

**A. Yes.**

Q. Do you remember that line of questions?

Does the -- the Bair Hugger blanket blow air directly onto the surgical site?

**A. The way how we put it on, I don't believe, because we actually -- we put our Bair Huggers on one -- after the patient is draped. And so let's say, for example, you have an upper-body cover, you have it taped right here across the patient's chest, and then you have all the OR drapes above it which themselves are -- are -- are -- are glued more or less to -- I don't know the right term any more -- to the skin. So I'm -- I'm not much worried about air blowing, getting out in that direction.**



Q. And in an arthroplasty, hip or knee, --

**A. Uh-huh --**

Q. -- do -- have you observed surgeons, orthopedic surgeons using drills or saws?

**A. Yeah.**

Q. Are the drills or saws used directly at the surgical site?

**A. Of course, yeah.**

Q. Do you know if those -- if the drills or saws have any kind of internal fan, cooling fan?

MR. ASSAAD: Objection, lack of foundation.

**A. I don't. I don't.**

Q. When you -- when you've seen them used, do they generate any type of movement or activity or, you know, physical mechanical activity in the -- in the immediate --

**A. They're all really loud, so I assume, yes. But the physical activity they generate, I don't know; I mean you see water spraying all over the place, but that's the only thing we see.**

Q. Do you see --

**A. Yeah. Because they use -- they use --**

**How do you call these things, the opposite of suction? If you -- gosh, it's getting late now. If you put water into a surgical area, and then of**



**course you use a drill, then it starts splashing all over the place.**

Q. And the --

Is there something to suck out the water?

**A. Yes, there is.**

Q. And -- and all of that's happening right at the surgical site.

**A. Yes.**

Q. Again, earlier you were asked about the -- you know, the -- the -- you -- you would never -- you would never want to introduce something that would cause harm; right?

**A. Correct.**

Q. Everything, pretty much, in medicine has the potential to cause some harm; right?

**A. Correct.**

MR. ASSAAD: Objection, lack of foundation, assumes facts not in evidence.

Q. For example, general anesthesia, there are -- there are potential complications and potential bad outcomes for -- for some people from getting general anesthesia; right?

**A. Rarely nowadays, but yes.**

Q. Rarely. But for the --

In those rare events, that -- that's harm;



right?

**A. Absolutely.**

Q. And because of those -- that rare occasion where somebody might be harmed, would that in your mind justify the i -- the -- deciding, well, we're never going to use general anesthesia?

**A. No.**

Q. In fact, all of medicine involves a balancing of -- of risks --

**A. Yeah.**

Q. -- and benefits.

**A. Every drug, every device does.**

Q. In your resume you list a book chapter, I think it's your -- your -- the very first book chapter you list on page 43, that's Exhibit 237, and the title is "Does intraoperative core hypothermia increase the incidence of surgical wound infections and prolong hospitalization?" And the -- the date is 1994; is that right?

**A. I still haven't found it yet.**

Q. Number one.

**A. Oh, number one. Okay.**

Q. The very first one.

**A. Yes. Correct.**

Q. Okay. And here's -- here's my question:

Were -- there was -- you -- some earlier questions about your 1996 study being the first randomized controlled trial that -- that demonstrated that the main -- maintenance of normothermia reduced infections. In 1994, when you wrote this chapter, did you have -- did you offer any answers to that -- to that first question, does intraoperative core hypothermia increase the incidence of surgical wound infections?

**A. I probably had no clue then. No. I -- I don't -- I don't know. This is such an old chapter --**

Q. I -- I -- I -- I -- I -- I understand, and my -- my -- my -- my -- my question, though, is do you recall back in 1994 when you wrote this chapter that there was some -- there were --

**A. Huh-uh.**

Q. -- there was some reason for you and your -- your co-authors of this chapter to be concerned about the issue as -- of -- of whether intraoperative core hypothermia could increase the incidence of surgical wound infections?

**A. Yeah, because --**

MR. ASSAAD: Object to the form, object to the preamble, lack of foundation, assumes facts not in evidence.



**A. I mean in '94 we were about to start our -- or we were in the middle, actually, of our large -- not "large" -- of our 200-patient study. I -- I assume what we did here is look at basic science indications, so how hypothermia affects immune function and other things. But that's all I can think of. There was no other evidence at that time.**

Q. Earlier you -- you were asked about patients that -- that -- surgeries -- surgical procedures where you -- you don't think warming is necessary. You mentioned eyes. Then you were asked about procedures under an hour, and I -- I don't want to put words in your mouth, but what -- what was your -- what was your answer to whether procedures under an hour should have active warming or not?

**A. I think I said it's not absolutely necessary because what you get in the first hour is redistribution hypothermia, and you get that due to induction of anesthesia and you almost get that no matter whether you warm or don't.**

Q. Are there circumstances where you would nevertheless recommend -- recommend active warming for procedures of less than an hour?

**A. I have to tell you that here at the Cleveland Clinic we warm everybody, even the ones that are less than an hour. But then, of course, very few procedures here are less than an hour. I am -- I'm --**

**I'm only little bit hesitant, and I was before as well, only because the whole thing -- the whole discussion about prewarming and redistribution hypothermia has changed a little bit over the past few years, so what we thought 10 years ago might not be so true any more. And redistribution isn't as much as it used to be. So it's an area that still has to be researched quite a bit in my mind, and that's why I'm hesitant when these questions come. But I think at this given point in time I would -- most surgeries that are less than an hour, I wouldn't do much in regards to active warming.**



Q. What -- what do you mean the "redistribution isn't as much as it used to be?"

**A. When we did our first studies about 15, 20 years ago, we actually published that anesthesia causes a 1- to 1.5-degree redistribution hypothermia, and this is not what we see nowadays in our data. So studies in the last six, seven years actually only show .5, .7, maximum .8 degrees of redistribution hypothermia.**

Q. What -- what are the reasons for that?

**A. I think that patients come to surgery maybe in better conditions nowadays as opposed to 20 years ago. So 20 years ago patients didn't come from home, they usually for any type of surgery will be in the hospital a few days before surgery, so they would already be hypervolemic and probably uncomfortable and, and, and, and, so -- and all -- all these things, of course, affect how induction of anesthesia pans out. And now when patients come from home, they probably have a very good overall body-heat content already, they aren't hyp -- they shouldn't be hypothermic because they're awake. So it's not totally clear to us yet why that has changed so much, but it's clear that it has changed. It's -- it's -- it's obvious in many publications.**



Q. You remain an advocate of active warming.

MR. ASSAAD: Objection to form. Objection to form.

Q. Is that correct?

**A. Yes, I do. I am because --**

**I mean we always talk about evidence-based medicine, but we have so little evidence in any type of field. I mean we all try to get as much as we do, and that's why we are now doing this -- this large Protect study, because we want to get the evidence. But I also believe that a little bit still in -- in**

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**medicine is art and the way you -- you understand the existing data. So yes, I -- I do still believe in these things.**

Q. And are -- are you including the clinical judgment applied to --

**A. Yes, absolutely.**

Q. -- existing data where maybe you can't connect all the dots empirically but --

**A. Yes.**

Q. -- your clinical judgment comes into play?

**A. Yeah. And you can also only interpret data in the context of the time, so what might have been very true 20 years ago might not be now, and vice versa, and conditions change, types of surgery change, patients change, we change. So I think every physician needs to put together -- look at the data as -- as -- as a whole and interpret it for themselves.**

MR. GORDON: Okay. Thank you. I'm done.

THE WITNESS: You're welcome.

MR. ASSAAD: I have a few follow-up questions.

THE WITNESS: Yeah.

(Discussion off the stenographic record.)

BY MR. ASSAAD:

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Q. You say to do the -- the -- the 1996 test today would be unethical.

**A. Yes.**

Q. Okay. And that's why you're going to China to do the studies, because they don't have forced-air warming as a standard of care; correct?

**A. No. Absolutely not. The -- the study -- even the stud --**

**First of all, the study will happen here at the Cleveland Clinic as well, and the main reason of the study is to look at a much lesser degree of hypothermia. So while in '96 patients were normally, as you said before, going down to 34.5 degrees, the limit for the current study is 35.5. So absolutely not.**

Q. There are areas in the world where forced-air warming or warming patients is not the standard of care.

**A. Correct.**

Q. Okay. So if you really want to redo the study, you could go to one of those countries and -- and -- and --

**A. Huh-uh.**

Q. -- do the study there.

**A. No, I cannot.**

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Q. Why not?

**A. I will not be able --**

**You will not be able to publish that anywhere in the western world.**

Q. Why not?

**A. Even if you --**

**That's just how -- that's just how it works. I don't know why. Even though you're right, it might not be standard of care, but even that I think is considered unethical, that you just go to a country that is underserved and --**

Q. Does fluid warming, is it as effective as forced-air warming?

**A. No.**

MR. GORDON: Object to the form of the question.

MR. ASSAAD: Basis. Basis.

MR. GORDON: In -- in all contexts? In what --

MR. ASSAAD: I'm asking in general. That's not a basis.

Go ahead and answer.

**A. I can answer that anyway. I believe it is not because greatest part of fluid warming is not considered active warming. So if you give only little**

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**bit of fluid and warm it to -- you can only warm fluids to 37 degrees because that's our -- safely our -- that's our body temperature. If you only give a little bit of fluid and it's only half a degree warmer than your core temperature, then you cannot transfer any heat with it. If you give eight liters in an hour, then of course you can transfer -- transfer heat even with fluids. But in the general setting it's not considered active warming. And we only do it here for very large cases like trauma or liver transplants, so --**

Q. And -- and you guys had -- you had a discussion with counsel regarding hypothermia causes an increase in transfusions; correct?

**A. Causes. Yes.**

Q. Okay. And -- and increased transfusions could possibly cause an increase in infection rates.

**A. Could be associated, yes.**

Q. Associated.

**A. I don't want to say "cause."**

Q. Okay. And if you are at 35 degrees for two hours, you agree with me based on the 2015 study that there's no increase of blood transfusions.

**A. No.**

Q. What would be the increase?

**A. I don't know, and I'm not sure that I can calculate it here. But if you are at 35 degrees for two hours, you should be at considerable risk for blood loss.**

Q. What about for one hour?

**A. Probably less.**

Q. Isn't it -- isn't it a 1.0 odds ratio? If you look at your paper, two degrees for one hour gives an odds ratio of 1.0; correct?

**A. Where is the paper? I can't remember.**

MS. DIFRANCO: What's the exhibit number?

MR. ASSAAD: Exhibit 243.

**A. I'm slowly zoning out here, that's why I'm not concentrating.**

**I don't know what we used as odds ratio -- as -- as reference.**

Q. You used 36 degrees at one hour.

**A. Yeah. I -- I --**

**You know, honestly, I think I would have to go over that with our statistician.**

Q. Well isn't an odds ratio the increased risk of something occurring?

**A. It is. But I can't see what one -- or I --**

**At least at this point in time any more I don't understand exactly what the one was. The**



**area --**

**It's not one degree. The area under 37 degrees times hour.**

Q. If you don't understand the study, that's fine. We can -- we can move on.

**A. Yes, let's move on.**

**(Exhibit 247 was marked for identification.)**

BY MR. ASSAAD:

Q. What's been marked as Exhibit No. 247 is an e-mail chain, and I want you to turn to the second page where there's an e-mail from Dr. Sessler to numerous people at 3M, and you're copied on it as well, on November 20th, 2012.

THE WITNESS: That's this one?

MS. DIFRANCO: This one, yes. Yes.

**A. Yeah.**

Q. Do you recall receiving this e-mail?

**A. I don't, but I'm on there.**

Q. Okay. It says -- from Daniel Sessler. It says, "Hi Folks,

"One of the points Andrea and I tried to make at the KOL meeting in Washington is that the evidence for hypothermia-related complications mostly does not meet current research guidelines for



reliability and that previous studies were done with much larger temperature differences than are currently allowed."

I want to focus on the next paragraph.

"Others have noticed the same thing. See, for example, page 13 of the current issue of the ASA newsletter which includes the following: 'The normothermia measure has the weakest evidence supporting its ability to improve outcomes and is a complex, non-intuitive measure involving multiple inclusion and exclusion criteria.' And in a different article on page 16: 'outcome measures -- such as mortality and readmission -- have moved to center stage, and process measures, such as antibiotic timing, are less and less seen as acceptable new measures of quality.'"

Did I read that correctly?

**A. Yeah.**

Q. So are you telling me today that your testimony is you're not aware of other people -- I mean I -- strike that.

I assume you read the ASA newsletter; correct?

**A. Very rarely.**

Q. Okay. Did you have any discussions with Dr.



Sessler regarding this e-mail with respect to, "Hey, what are you talking about? Other people have issues with normothermia and its weak evidence?"

**A. I don't recall it, but I probably have.**

Q. Okay. So it shouldn't be something new today when I asked you the question that other people have issues with normothermia and its effect on outcomes.

MR. GORDON: Object to the form of the question.

**A. They are. It could be quite new because I'm not remembering every e-mail from 2012.**

Q. But you'd heard something about it back in 2012. You -- you got copied on this e-mail; correct?

**A. Yes.**

Q. And do you read e-mails you receive from Dr. Sessler?

**A. Mostly.**

Q. Now you said that Cleveland Clinic is -- is moving towards more disposables; correct?

**A. Yes.**

Q. They could --

They charge the patient for those disposables; correct?

**A. I assume it's part of the patient charge.**

Q. Okay. So they, for example, buy the blanket from either Stryker or Bair Hugger for whatever the cost is, and they mark it up and -- and charge it to the patient.

**A. I don't know whether we directly charge every single one of that items or whether it's part -- a part of an anesthesia package type of thing. So I don't -- I don't think that, if you look at your invoice from the Cleveland Clinic, that you see everything, the IV and everything in there.**

Q. Well you do see Bair Hugger blankets.

**A. I don't know.**

Q. Okay.

**A. I don't know.**

Q. Do you know the number of patients that -- or number of total hip or total -- or total knee arthroplasty patients that result in some sort of cardiac injury after surgery?

**A. I can make a very good assumption, which is 10 percent.**

Q. Ten percent have a cardiac injury.

**A. Ten per --**

**Eight to 10 percent will probably, and especially after the big joints, yes.**

Q. And if those patients are warmed, what's the



reduction in cardiac injury?

**A. I don't know.**

Q. Okay. You don't --

If any. You don't know. There might be no reduction; correct?

**A. There --**

**From what I know, I assume there is some, but I don't know. That's why we do the study.**

Q. Are you currently aware that 3M has acquired the exclusive right to a conductive blanket?

**A. I'm not.**

Q. No discussions with 3M?

**A. No.**

MR. ASSAAD: That's all I have.

MR. GORDON: Thank you.

MR. ASSAAD: Thank you.

MS. DIFRANCO: All right. We'll waive the witness's signature.

THE REPORTER: Off the record, please.

(Deposition concluded.)



CERTIFICATE

I, Richard G. Stirewalt, hereby certify that I am qualified as a verbatim shorthand reporter, that I took in stenographic shorthand the deposition of DR. ANDREA KURZ at the time and place aforesaid, and that the foregoing transcript is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability.

Dated at Deerwood, Minnesota, this 19th day of January, 2017.

RICHARD G. STIREWALT
Registered Professional Reporter
Notary Public